UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419 Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO: Suits Naming Specialty Surgery Center, Crossville, PLLC	)	

ANSWER OF SPECIALTY SURGERY CENTER, CROSSVILLE, PLLC, KENNETH R. LISTER, MD, AND KENNETH LISTER, MD, PC

For their Answer to the Master Complaint, the Defendants Specialty Surgery Center, Crossville, PLLC ("SSC"), Kenneth R. Lister, MD ("Dr. Lister"), and Kenneth Lister, MD, PC ("Dr. Lister's Practice") (collectively, the "Defendants"), state as follows:

I. INTRODUCTION

1. The Defendants admit that this multidistrict litigation arose as the result of an outbreak of fungal meningitis and other infections. The Defendants admit that the Centers for Disease Control and Prevention ("CDC") reported that individuals in at least 20 states were affected by the outbreak and that the outbreak caused 64 deaths. The Defendants are without knowledge or information sufficient to form a belief as to whether the outbreak caused over 64 deaths as alleged in paragraph 1. The Defendants admit that the CDC has reported that 751 people have been diagnosed with fungal meningitis, fungal infections and/or abscesses as part of the outbreak. The Defendants are without knowledge or information sufficient to form a belief as to whether more than 751 people have been diagnosed with fungal meningitis, fungal infections and/or abscesses, and other injuries as alleged in paragraph 1.

2. Admitted, based on public reports from these agencies.

3. The Defendants are without knowledge or information sufficient to form a belief as to whether "no one" disputes the allegations of paragraph 3. The Defendants admit, based upon information and belief, that the New England Compounding Company, Inc. ("NECC") compounded the contaminated medication that caused the Plaintiffs' alleged injuries and damages. The Defendants, at this point, admit, based upon information and belief, that the conditions at NECC's facility contributed to the outbreak. The Defendants affirmatively state that they have had limited discovery of NECC related to the exact cause of the outbreak. To the extent the allegations of paragraph 3 suggest the Defendants engaged in wrongdoing or contributed to the alleged injuries and damages, those allegations are denied.

4. The Defendants admit, based upon information and belief, that Liberty Industries, Inc. ("Liberty") designed and constructed the cleanroom(s) used to compound the contaminated methylprednisolone acetate ("MPA") that caused the Plaintiffs' injuries. The Defendants admit, based upon information and belief, that there were defects in the cleanroom(s) that made the contamination of the MPA more likely. However, the Defendants are without knowledge or information sufficient to form a belief as to whether the defects in the cleanrooms were caused by Liberty's construction or NECC's subsequent actions.

5. The Defendants are without knowledge or information sufficient to form a belief as to whether UniFirst provided cleaning services to Ameridose. The Defendants admit, based upon information and belief, the remaining allegations of paragraph 5.

6. The Defendants admit that SSC purchased MPA from NECC and that Dr. Lister administered it to some of the Plaintiffs. The Defendants admit that NECC's contamination of the medication caused some of the Plaintiffs' injuries and damages. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants deny "disregarding prevailing industry guidelines and Massachusetts pharmacy regulations" when purchasing the medications. The Defendants deny that SSC used fake patient names to purchase the medications. The Defendants deny that SSC purchased the medication "out of convenience and greed." The Defendants deny that identifying individual patients who would receive each vial of MPA is a safeguard. The Defendants are without knowledge or information sufficient to form a belief as to whether the MPA from NECC was cheaper than the

equivalent medication manufactured by Pfizer. Any allegation in paragraph 6 not specifically admitted is denied.

7. No response is required to paragraph 7.

8. No response is required to paragraph 8.

9. No response is required to paragraph 9.

II. JURISDICTION AND VENUE

10. Denied.

11. Admitted, based upon the rulings of the Court to this point in the MDL.

12. Admitted.

13. Denied.

14. The Defendants deny that the consolidation of cases for pretrial purposes in the District of Massachusetts by the Judicial Panel on Multidistrict Litigation makes the District of Massachusetts the proper venue for filing suit against the Defendants. Subject to and without waiving any defenses based upon lack of personal jurisdiction, the Defendants admit that filing the Master Complaint, a self-described administrative tool, in the District of Massachusetts is proper.

15. The Defendants admit that venue for pretrial administration of the cases is proper pursuant to the ruling of the Judicial Panel on Multidistrict Litigation designating the District of Massachusetts as the centralized venue for this MDL. The Defendants do not waive their right, pursuant to *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998), to have these cases transferred to Tennessee for trial.

16. Admitted.

III. PARTIES

Plaintiffs

17. The Defendants admit that some Plaintiffs suffered death, injury, or distress caused by the contaminated MPA from NECC. The Defendants admit that Dr. Lister unknowingly administered the contaminated MPA to some Plaintiffs. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants are without knowledge or information sufficient to form a belief as to whether ALL Plaintiffs suffered injuries described in paragraph 17.

18. To the extent paragraph 18 alleges wrongdoing on the part of the Defendants, those allegations are denied. No response is required to the remaining allegations of paragraph 18.

Defendants

19. No response is required to paragraph 19.

20. The allegations of paragraph 20 are not asserted against the Defendants. No response is required.

21. The allegations of paragraph 21 are not asserted against the Defendants. No response is required.

22. The Defendants admit that the chart in paragraph 22 appears to be a list of clinics that received MPA from one of the three recalled lots of MPA, as reported by the CDC, with clinics who were participating in mediation as of November 2013 omitted.

23. The Defendants admit that SSC purchased the recalled MPA from NECC and that Dr. Lister administered the MPA to some of the Plaintiffs. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was

contaminated. The Defendants deny that Dr. Lister or Dr. Lister's Practice purchased MPA from NECC. The Defendants deny that all physicians at SSC were employees or agents of SSC and that all physicians were acting within the course and scope of any employment or agency of the Defendants. The Defendants admit that, when SSC decided to purchase MPA from NECC, SSC's Nursing Director was an employee of SSC. The Defendants deny that Dr. Lister was an employee or agent of SSC. He was a member of SSC. The Defendants admit that, if the Plaintiffs establish that an agency or employment relationship existed, they may be liable for the actions of their employees or agents.

IV. FACTUAL BACKGROUND

A. The Conigliaro Family Businesses.

1. Conigliaro Industries Recycling Plant.

24. to 28. The allegations of paragraphs 24 to 28 are not asserted against the Defendants. No response is required.

2. Gregory Conigliaro, Barry Cadden, and Douglas Conigliaro Founded NECC.

29. to 34. The allegations of paragraphs 29 to 34 are not asserted against the Defendants. No response is required.

3. Medical Sales Management.

35. to 36. The allegations of paragraphs 35 and 36 are not asserted against the Defendants. No response is required.

4. Ameridose.

37. to 40. The allegations of paragraphs 37 to 40 are not asserted against the Defendants. No response is required.

5. Alaunus Pharmaceuticals.

41. The allegations of paragraph 41 are not asserted against the Defendants. No response is required.

42. No response is required to paragraph 42.

B. Background on Compounding Pharmacies.

43. Denied. According to the FDA website:

> In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.[1]

44. The Defendants admit, based upon information and belief, the allegations of paragraph 44.

45. Denied.

46. The Defendants admit, based upon information and belief, that compounding pharmacies generally follow testing guidelines established by the United States Pharmacopeia Convention, "a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide."[2] The Defendants are without knowledge or information sufficient to form a belief as to whether the International Academy of Compounding Pharmacists ("IACP") is an "industry group." The Defendants admit that the IACP said in an October 4, 2012, statement that compounding pharmacies were "expected" to adhere to USP 797.[3] The

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[1] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm, last accessed September 16, 2014.
[2] http://www.usp.org/about-usp, last accessed September 16, 2014.
[3] http://www.iacprx.org/?277, last accessed September 16, 2014.

Defendants are without knowledge or information sufficient to form a belief as to whether other Massachusetts compounding pharmacies, including Microtest Laboratories, typically test more than the number of samples required by USP standards to confirm sterility.

47. The Defendants are without knowledge or information sufficient to form a belief as to the purpose or intended scope of unspecified "compounding industry standards."

C. The Risks of Pharmacy Compounding.

48. Denied.

49. The Defendants admit that CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections in 2002 and that the "Editorial Note" section states that "[p]urchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that is licensed in their state and that follows appropriate measures to ensure that injectable products are free of contamination." The Defendants deny that this is the entirety of the publication. The Defendants further deny any suggestion that the existence of the report placed a duty on them or establishes the recognized standard of acceptable professional practice. Further, NECC was licensed by the state of Tennessee and assured the Defendants that it followed measures to ensure injectable products were free of contamination, including USP 797.

50. The Defendants admit that *USA Today* published an article titled "Safety concerns grow over pharmacy-mixed drugs" and that the article discusses concern among "critics and regulators" that compounding pharmacies "are not held to the same

quality and safety rules as FDA-regulated drug companies." But, the Defendants affirmatively state that the article also notes that (1) "regulators have long allowed [compounding] because 'the vast majority of pharmacies . . . provide a valuable medical service,'" (2) "proponents say compounding pharmacies overall are safe," (3) "several states are tightening their rules overseeing firms that compound drugs," and (4) "the FDA has stepped in when it decides a pharmacy has crossed the line and become a drug manufacturer." The Plaintiffs omitted this language from the Master Complaint. The Defendants are without knowledge or information sufficient to form a belief as to whether the article was a front-page story. The Defendants deny any suggestion that the existence of a 2005 *USA Today* article placed a duty on them or establishes the recognized standard of acceptable professional practice.

51. The Defendants admit that the FDA published a study titled "Limited FDA Survey of Compounded Drug Products" in 2006. The Defendants admit that the study reported that the FDA collected 73 finished drug products from compounding pharmacies across the country during unannounced visits, but the FDA excluded 37 of the samples from the study because they were deemed unusable for various reasons. The Defendants admit that the study reported that, of the 36 samples tested, 12 (33%) failed analytic testing, but note further that "[m]ost of the products that failed analysis did so due to sub or super-potency . . . or a lack of uniformity of individual dosage units [and not because of contamination]." The Defendants also note that the study indicates that its "results . . . suggest a problem with the quality of certain compounded drug products," and "[t]he majority of the finished compounded product samples analyzed in th[e] survey were hormone therapy products." The article also states that the "FDA has

long recognized that traditional pharmacy compounding serves an important public health function" and that the "FDA has historically exercised enforcement discretion and generally has not taken enforcement action against pharmacies engaged in traditional compounding." The Defendants deny any suggestion that the existence of a 2006 study of 36 samples, mostly hormone replacements, placed a duty on them or establishes the recognized standard of acceptable professional practice.

52. The Defendants admit that the FDA published an article titled "The Special Risks of Pharmacy Compounding" in May 2007. The article references adverse events involving compounded products and notes the concern of the FDA over compounding operations operating "clearly outside the bounds of traditional pharmacy." The article further notes that Steve Silverman, Assistant Director of Center for Drug Evaluation and Research Office of Compliance, said that "doctors may not understand that they are receiving compounded products." The Defendants deny any suggestion that the existence of the article placed a duty on them or establishes the recognized standard of acceptable professional practice.

53. The Defendants admit that the FDA posted an educational video on YouTube.com regarding concerns over the quality of compounded drugs. The video states that "today, more than 30 million prescription drugs are compounded annually - many by honest, hard-working pharmacists who provide a much-needed service to their patients," and "there are both risks and benefits associated with [compounded drugs]." The Defendants deny any suggestion that the existence of a video on YouTube.com placed a duty on them or establishes the recognized standard of acceptable professional practice.

54. The Defendants admit that the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP"), and other medical societies published a joint report regarding drug shortages, and that the report included an article written by the ASHP with the quote included in paragraph 54. The Defendants further note that the article concluded that "[e]ach health system must determine its philosophy on purchasing from . . . compounding pharmacies." The Defendants deny any suggestion that one paragraph from an eight-page exhibit to a 52-page report placed a duty on them or establishes the recognized standard of acceptable professional practice.

55. The Defendants admit that the CDC published a report in May 2012 regarding fungal infections arising from medications obtained from a compounding pharmacy and that the report states that "contamination of compounded sterile preparations has caused outbreaks." The article noted that "[s]ince 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products." The Defendants note that the article does not address the hundreds of adverse events associated with products from FDA-registered drug companies. The report further states that "[c]ompounded sterile preparations must be prepared according to aseptic practices recommended by organizations such as the United States Pharmacopeia, as stated in United States Pharmacopeia-National Formulary (3)." The Defendants deny any suggestion that the existence of the report placed a duty on them or establishes the recognized standard of acceptable professional practice. Regardless, NECC represented to the Defendants that it was USP 797-compliant.

D. Meningitis

56. The Defendants admit, based upon information and belief, that meningitis is an *inflammation* (not infection) of the meninges, the membranes covering the brain and spinal cord. The inflammation is often caused by infection. The Defendants admit, based upon information and belief, that symptoms of meningitis include fever, chills, altered mental status, nausea, vomiting, sensitivity to light, severe headache, and neck stiffness. The Defendants admit, based upon information and belief, that meningitis can be diagnosed by testing the patient's cererbrospinal fluid obtained by lumbar puncture. The Defendants admit, based upon information and belief, that testing of the cerebrospinal fluid may reveal the infection's cause, which may assist in determining the best course of treatment. The Defendants admit, based upon information and belief, that testing of the cerebrospinal fluid is not the only method of diagnosing meningitis. The Defendants admit, based upon information and belief, that meningitis *can* be diagnosed based on the patient's symptoms alone but such a diagnosis is often unreliable. The Defendants admit, based upon information and belief, that brain damage, subdural effusion, hearing loss, hydrocephalus, and seizures are *possible* complications of meningitis. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding their alleged symptoms, diagnosis, treatment, and injuries.

57. The Defendants admit, based upon information and belief, the allegations of paragraph 57. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding their alleged symptoms, diagnosis, treatment, and injuries.

58. The Defendants admit, based upon information and belief, that an infection that eventually causes meningitis can spread through the blood to the spinal column. The Defendants admit, based upon information and belief, that meningitis can be caused by the introduction of bacteria, virus, or fungus into the central nervous system or from "an infected body site infection" near the central nervous system. The Defendants deny that these are the only possible routes of introduction of the pathogens that cause meningitis. The Defendants admit, based upon information and belief, that symptoms of meningitis can include fever, chills, altered mental status, nausea, vomiting, sensitivity to light, severe headache, and neck stiffness. The Defendants admit, based upon information and belief, that death may result from fungal meningitis. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding their alleged symptoms, diagnosis, treatment, and injuries.

59. The Defendants are without knowledge or information sufficient to form a belief as to whether a "typical" incubation period for fungal meningitis is known or generally accepted by the medical community. The Defendants admit, based upon information and belief, that symptoms of fungal meningitis can be mild. The Defendants admit, based upon information and belief, that performing a lumbar puncture can assist in determining whether a patient has meningitis, and, if so, what type. The Defendants are without knowledge or information sufficient to form a belief as to whether the treatment type, length, or laboratory tests for fungal meningitis vary based on the type of fungus. The Defendants admit, based upon information and belief, that treatment for fungal meningitis can involve long courses of high-dose antifungal medications. The

Defendants are without knowledge or information, at this stage, to form a belief as to whether such courses of treatment are "typical." The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding their alleged symptoms, diagnosis, treatment, and injuries.

E. The Outbreak and Its Aftermath.

60. The Defendants admit, based upon information and belief, that the Tennessee Department of Health ("Tenn. DoH") notified the CDC of a patient with fungal meningitis following an epidural steroid injection. The Defendants admit, based upon information and belief, that the CDC's investigation of the outbreak began in September 2012. The Defendants are without knowledge or information sufficient to form a belief as to the exact timing of the Tenn. DoH's notification of the CDC or confirmation that the index patient's meningitis was caused by fungus. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding their alleged symptoms, diagnosis, treatment, and injuries.

61. The Defendants admit, based upon information and belief, the allegations of paragraph 61. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding their alleged symptoms, diagnosis, treatment, and injuries.

62. The Defendants admit, based upon information and belief, that, by September 27, 2012, the Tenn. DoH in collaboration with the CDC and the North Carolina Department of Health and Human Services, had identified nine total patients with fungal meningitis who had received epidural steroid injections from one of the three contaminated lots of MPA from NECC (lot numbers 05212012@68, 06292012@26, and

08102012@51). The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding their alleged symptoms, diagnosis, treatment, and injuries.

F. FDA and Massachusetts Board of Registration in Pharmacy Begin Investigating NECC.

63. The Defendants admit, based upon information and belief, the allegations of paragraph 63.

64. The Defendants admit that, on September 26, 2012, NECC recalled three lots of preservative-free MPA: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013. The Defendants admit, based upon information and belief, that approximately 3,000 doses were quarantined or returned through the recall. The Defendants admit, based upon information and belief, that approximately 13,534 patients were exposed to the contaminated MPA. The Defendants admit that NECC faxed recall notices to the facilities that received the contaminated lots beginning on September 26, 2012.

65. The Defendants admit that the Massachusetts Board of Registration in Pharmacy ("Mass. BoP") reported that, when investigators arrived at NECC's facility on September 26, 2012, NECC employees were cleaning compounding areas and conducting environmental testing. The Defendants are without knowledge or information sufficient to form a belief as to whether investigators detected signs of "black contamination" in the compounding areas.

66. The Defendants admit that the Mass. BoP reported that, after September 26, 2012, the majority of NECC's employees were no longer on site. The Defendants admit that the Mass. BoP reported that NECC terminated many of its staff. The

Defendants are without knowledge or information sufficient to form a belief as to when the employees were terminated or whether the employees were on site on September 26, 2012.

67. The Defendants admit, based upon information and belief, that FDA and Mass. BoP investigators returned to NECC's facility on October 1, 2012. Based upon information and belief, the FDA and Mass. BoP *began* their joint investigation of NECC as early as 2002. The Defendants admit, based upon information and belief, that, during the October 1, 2012, investigation, investigators were shown samples of MPA that were labeled as patient-specific, but the associated documents were not individual prescriptions. The Defendants admit, based upon information and belief, that the documents were lists of patients generated by a clinical facility and provided to NECC during the ordering process. The Defendants admit, based upon information and belief, that NECC stated the lists were considered to be an authorized prescription by a physician. The Defendants admit that the Mass. BoP opined that this practice is not in accordance with Massachusetts regulations.

68. The Defendants admit, based upon information and belief, the allegations of paragraph 68.

69. The Defendants admit, based upon information and belief, the allegations of paragraph 69.

G. NECC Surrenders Its Pharmacy License and Recalls All of Its Products.

70. The Defendants admit, based upon information and belief, that, on October 3, 2012, the Mass. BoP instituted a voluntary recall of all intrathecal products compounded by NECC. The Defendants admit, based upon information and belief, that

NECC voluntarily surrendered its license on October 3, 2012. The Defendants are without knowledge or information sufficient to form a belief as to when NECC ceased all production.

71. The Defendants admit, based upon information and belief, the allegations of paragraph 71.

72. Admitted.

73. Admitted.

H. FDA and Massachusetts Board of Pharmacy's Findings.

74. The Defendants admit, based upon information and belief, the allegations of paragraph 74.

75. The Defendants admit, based upon information and belief, the allegations of paragraph 75.

I. Mass. BoP's Preliminary Findings.

76. Admitted.

77. The Defendants admit, based upon information and belief, the allegations of paragraph 77.

78. The Defendants admit, based upon information and belief, the allegations of paragraph 78.

79. The Defendants admit, based upon information and belief, the allegations of paragraph 79.

80. The Defendants admit, based upon information and belief, the allegations of paragraph 80.

81. The Defendants admit that the Mass. BoP reported that NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication and admit that the Mass. BoP reported that this practice violated state law.

82. The Defendants admit, based upon information and belief, the allegations of paragraph 82.

83. The Defendants admit, based upon information and belief, that NECC failed to properly seal its cleanrooms. The Defendants admit that this could have allowed contaminants to infiltrate the room and could have exposed drugs to contamination. The Defendants are without knowledge or information sufficient to form a belief, as this time, as to whether the failure to properly seal the cleanrooms in fact allowed contaminants to infiltrate the room or exposed drugs to contamination.

84. The Defendants admit, based upon information and belief, that the Mass. BoP reported that NECC's powder hoods were not thoroughly cleaned pursuant to USP 797. The Defendants are without knowledge or information sufficient to form a belief as to whether this also violated NECC's standard operating procedures. The Defendants admit that the Mass. BoP reported visually observing residual powder which could subsequently lead to contamination of compounded medications.

85. The Defendants admit, based upon information and belief, the allegations of paragraph 85.

86. The Defendants admit, based upon information and belief, the allegations of paragraph 86.

J. FDA's Initial Findings and Form 483 Report.

87. The Defendants admit that, on October 18, 2012, the FDA reported that the FDA and CDC had confirmed the presence of *Exserohilum rostratum* in unopened vials of MPA from Lot #08102012@51.

88. Admitted.

89. The Defendants admit, based upon information and belief, the allegations of paragraph 89.

90. The Defendants admit, based upon information and belief, the allegations of paragraph 90.

91. The Defendants admit, based upon information and belief, the allegations of paragraph 91.

92. The Defendants admit, based upon information and belief, the allegations of paragraph 92.

93. The Defendants admit, based upon information and belief, the allegations of paragraph 93.

94. The Defendants admit, based upon information and belief, the allegations of paragraph 94.

95. The Defendants admit, based upon information and belief, the allegations of paragraph 95.

96. The Defendants admit, based upon information and belief, the allegations of paragraph 96.

97. The Defendants admit, based upon information and belief, the allegations of paragraph 97.

98. The Defendants admit, based upon information and belief, the allegations of paragraph 98.

99. The Defendants admit that the FDA reported that the tacky mat located within the entrance of one of the prep rooms, at the transition to the warehouse, was brown and soiled. The Defendants are without knowledge or information sufficient to form a belief as to whether the tacky mat was "filthy."

100. The Defendants admit, based upon information and belief, the allegations of paragraph 100.

K. The Investigation Grows, Covering Other Drugs and Related Corporate Entities.

1. Mass. BoP Shuts Down Ameridose and Suspends Insiders' Pharmacy Licenses.

101. The Defendants admit, based upon information and belief, the allegations of paragraph 101.

2. FDA Confirms Other NECC Products Are Contaminated.

102. The Defendants admit, based upon information and belief, the allegations of paragraph 102, assuming that the Plaintiffs meant "ophthalmic" instead of "opthalmic" and "fumigatus" instead of "funigatus."

103. The Defendants admit, based upon information and belief, the allegations of paragraph 103.

3. Board of Pharmacy Revokes Cadden, Chin, and Conigliaro Pharmacy Licenses.

104. The Defendants admit, based upon information and belief, the allegations of paragraph 104.

L. FDA and Mass. BoP Investigate Ameridose and Alaunus Pharmaceuticals.

105. The Defendants admit, based upon information and belief, the allegations of paragraph 105.

106. The Defendants admit, based upon information and belief, the allegations of paragraph 106.

107. The Defendants admit, based upon information and belief, the allegations of paragraph 107.

108. The Defendants admit, based upon information and belief, the allegations of paragraph 108.

1. FDA Confirms Ameridose's Products are Contaminated.

109. Admitted.

110. Admitted.

111. The Defendants admit, based upon information and belief, the allegations of paragraph 111.

112. The Defendants admit that the FDA reported that there was no documented evidence to suggest that Ameridose performed a health hazard evaluation to assess the potential quality impact of microbiological isolates identified during sterility testing. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 112. The portions of Exhibit C apparently relied upon by the Plaintiffs for the information in this paragraph contain redactions that may impact the meaning of those portions of the FDA report.

113. The Defendants admit, based upon information and belief, the allegations of paragraph 113.

114. The Defendants admit, based upon information and belief, that, in 2012, 45 environmental microbiological excursions (bacteria and mold) were isolated from critical areas such as personnel fingers inside class 100 hoods and controlled manufacturing areas during the manufacture of sterile injectable drug products. The Defendants are without knowledge or information sufficient to form a belief as to whether the employee's fingers were uncovered. The Defendants admit, based upon information and belief, that there is no evidence that Ameridose initiated a health hazard evaluation to assess the potential quality impact of these potential contaminates. The Defendants admit, based upon information and belief, that, on at least one occasion, Ameridose re-filtered stock solutions involved in a sterility failure before releasing final drug product lots for patient use.

115. The Defendants admit, based upon information and belief, that Ameridose received at least 29 adverse event reports associated with its products that included reports of low potency, post-partum hemorrhaging, over-sedation, respiratory distress, and lack of effect. The Defendants are without knowledge or information sufficient to form a belief as to whether Ameridose reported any of these adverse events to the FDA. The Defendants admit that the FDA reported that Ameridose classified at least some adverse event reports as "patient responses" or "non-complaints" and failed to investigate what the FDA described as a "trend of complaints."

116. The Defendants admit that the FDA reported that conditions of Ameridose's "aseptic core" were deficient. The Defendants admit that the FDA reported that Ameridose's gowns, eye protection, and gloves worn by employees were not sterile and were reused multiple times before being sent for cleaning. The Defendants admit

that the FDA reported that the environmental monitoring of class 100 hoods used to aseptically manipulate sterile drug products was not performed in association with daily operations. The Defendants admit that the FDA reported observing totes "placed in the location of penetrating leaks containing water." The Defendants admit that the FDA reported that walls in rooms used to prepare sterile drug products were cracked, corroded, and covered with adhesive material. The Defendants admit that the FDA reported observing brownish structures, whitish, opaque structures, rust, broken glass, foreign material, and thick residues that were orange, brown, and green in coloration within the front intakes of hoods used in the preparation of sterile drug products. The Defendants admit that the FDA reported that hoods with the conditions described in the preceding sentence were indicated to be clean and available for sterile processing. The Defendants are without knowledge or information sufficient to form a belief as to whether all hoods were indicated to be clean and available for processing.

117. The Defendants admit, based upon information and belief, the allegations of paragraph 117.

118. The Defendants admit, based upon information and belief, the allegations of paragraph 118.

M. Criminal and Congressional Investigations.

119. The Defendants admit, based upon information and belief, the allegations of paragraph 119.

120. The Defendants admit, based upon information and belief, the allegations of paragraph 120.

121. The Defendants admit, based upon information and belief, the allegations of paragraph 121.

122. Admitted.

N. Subsequent Litigation.

123. Admitted.

O. Current Case Counts.

124. The Defendants admit that the CDC estimates that 13,534 patients received MPA from one of the three contaminated lots, not "at least 14,000" as alleged in paragraph 124. The Defendants admit that as of the CDC's last update on October 23, 2013, the CDC reports 751 cases of fungal meningitis, paraspinal/spinal infection, stroke, and peripheral joint infection and 64 deaths (in nine states) linked to the steroid injections. The Defendants admit that the CDC reported cases in Florida, Georgia, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, and Virginia. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding their alleged symptoms, diagnosis, treatment, and injuries.

V. Factual Allegations

A. Liberty Industries, Inc.

125. The Defendants admit, based upon information and belief, the allegations of paragraph 125.

126. The Defendants admit, based upon information and belief, that in 2005, 2006, and 2008, Liberty constructed ISO Class 6, ISO Class 7, and ISO Class 8

cleanrooms at the Framingham, Massachusetts facility. The Defendants are without knowledge or information sufficient to form a belief as to whether Liberty constructed any ISO Class 5 cleanrooms at the facility.

127. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 127.

128. The Defendants admit, based upon information and belief, that there were defects in the cleanroom(s) constructed by NECC that made the contamination of the MPA more likely. However, the Defendants are without knowledge or information sufficient to form a belief as to whether the defects in the cleanrooms were caused by Liberty's construction or NECC's subsequent actions. The Defendants admit, based upon information and belief, that Liberty owed a duty to any foreseeable purchaser or recipient of products sold by NECC, including the Plaintiffs, to construct the cleanrooms to prevent the contamination of pharmaceuticals compounded within them.

129. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 129.

130. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 130.

131. 131. The Defendants are without knowledge or information sufficient to form a belief as to whether NECC requested and was denied repair of Liberty's defective work on numerous occasions. The Defendants admit that, in one cleanroom constructed by Liberty, a large opening in the wall provided access to a conveyor belt covered only with hanging vinyl slats. The Defendants admit, based upon information

and belief, that this opening provided a means of potential contamination and may have created problems maintaining the required air pressure in the cleanroom.

132. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 132.

133. The Defendants admit, based upon information and belief, the allegations of paragraph 133.

134. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 134.

135. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 135.

B. UniFirst Corporation.

136. The Defendants admit, based upon information and belief, the allegations of paragraph 136.

137. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 137.

138. The Defendants admit that UniFirst represents that it is an ISO 9001:2008 registered company. The Defendants admit, based upon information and belief, that UniFirst offers cleanroom cleaning and sterile and non-sterile garment services. The Defendants are without knowledge of information sufficient to form a belief as to the truth of the remaining allegations of paragraph 138.

139. The Defendants admit that, in its marketing materials, UniFirst acknowledges that “80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors.” The Defendants admit that UniFirst’s marketing

materials state, "[o]ver 70% of customers state that a poorly maintained restroom is enough reason not to patronize a business again." The Defendants admit that UniFirst marketing materials state, "[y]our facility — and your business image — will remain spotless, and your customers and employees will know you care." The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 139.

140. The Defendants are without knowledge or information sufficient to form a belief as to whether UniFirst "markets its products and services aggressively." The Defendants admit that UniFirst's website contains the statement quoted in paragraph 140.

141. The Defendants admit, based upon information and belief, that UniFirst entered into a Contamination Control Service Agreement ("CCSA") with NECC in May of 2011. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 141.

142. The Defendants admit, based upon UniFirst's 2011 contract with NECC, that UniFirst agreed to clean two cleanrooms at NECC's facility, including the anterooms. The Defendants admit, based upon UniFirst's 2011 contract with NECC, that UniFirst agreed to clean and sanitize the floors, walls, ceilings, and exteriors of hoods in the cleanrooms. The Defendants admit, based upon UniFirst's 2011 contract with NECC, that UniFirst agreed to provide the materials necessary to perform these services. The Defendants are without knowledge or information sufficient to form a belief as to whether UniFirst agreed to a "triple decontamination process" for each room.

143. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 143.

144. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 144.

145. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 145.

146. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 146.

147. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 147.

148. The Defendants admit that materials on UniFirst's website identify *Aspergillus niger* as "a mold utilized in the dairy industry and [*sic*] represents wet garment contamination." The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 148.

149. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 149.

150. The Defendants admit, based upon information and belief, that UniFirst should have known the dangers of allowing contaminants into the NECC facility. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 150.

C. Clinics, Hospitals, and Physicians.

151. The Defendants admit that some of the Plaintiffs sought treatment from some of the Defendants. The Defendants reserve and do not waive the right to respond

to each individual Plaintiff's allegations regarding whether the Plaintiffs sought treatment from a specific Defendant.

152. The Defendants admit that the Defendants and their employees or agents involved in the Plaintiffs' epidural steroid injection procedures were required to and did comply with the recognized standard of acceptable professional practice when selecting medication for the procedure and performing the procedure. The Defendants deny that Defendants not involved in the procedure and that did not select the medication owed a duty to the Plaintiffs arising from the procedure or the selection of medication. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding the alleged duty owed by the Defendants.

153. The Defendants admit that Dr. Lister administered MPA to some Plaintiffs from lots that were later determined to be contaminated. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA.

154. The Defendants admit that the MPA was injected into the Plaintiffs' epidural space. The Defendants deny that the epidural space is part of the central nervous system.

155. The Defendants admit that certain treatments and routes of medication administration may be less effective in treating infections of the central nervous system. The Defendants deny, based upon information and belief, that the MPA was injected into the Plaintiffs' central nervous systems.

156. The Defendants admit that steroids, including MPA, can act as immuno-suppressants. The Defendants are without knowledge or information sufficient to form a belief as to whether the immuno-suppressant effects of MPA can affect a patient's ability to fight off an infection caused by a pathogen in the MPA. The Defendants admit that, generally, suppression of the immune system makes a patient less able to fight off illness susceptible to suppression or eradication by the individual patient's immune system. But, the Defendants reserve the right to respond to each individual Plaintiff's allegations regarding the alleged results of the immuno-suppressant effects in a specific Plaintiff.

157. The Defendants deny any wrongdoing and affirmatively state that they complied with the recognized standard of acceptable professional practice when choosing to purchase MPA from NECC.

158. Denied.

159. Denied. MPA has been approved by the FDA.

160. Denied. MPA has been approved by the FDA.

161. Denied.

162. Denied.

163. The Defendants deny that NECC's drugs were "unregulated." The Defendants are without knowledge or information sufficient to form a belief as to whether MPA manufactured by FDA-registered drug manufacturers was available to the Defendants at the time of the Plaintiffs' procedures.

164. The Defendants admit, based upon information and belief, that NECC was required to comply with the laws in all states in which it was licensed, including Tennessee.

165. The Defendants admit, based upon information and belief, that some state laws required compounding pharmacies to obtain a patient-specific prescription prior to compounding medications. The Defendants admit, based upon information and belief, that NECC violated some of these laws but do not profess to be experts on the laws of other states. The Defendants affirmatively state that Tennessee law permits anticipatory compounding. *See* Tenn. Code Ann. § 63-10-204(4)(b).

166. The Defendants are without knowledge or information sufficient to form a belief as to what volumes of drugs were manufactured by NECC at specific points in time. The Defendants deny, based upon information and belief, that compounding medication in bulk was illegal under Tennessee law. *See* Tenn. Code Ann. § 63-10-204(4)(b). The Defendants deny that compounding sterile preparations in bulk is categorically riskier for a given patient than compounding on an individual basis.

167. Denied. The Defendants admit that SSC knew that NECC produced and marketed the quantities of drugs sold to SSC.

168. The Defendants admit, based upon information and belief, the allegations of paragraph 168 as they relate to Tennessee.

169. The Defendants admit that NECC produced medications in the amounts sold to SSC. The Defendants are without knowledge or information sufficient to form a belief as to whether this qualified NECC as a "wholesale distributor."

170. Denied.

171. Denied.

172. The Defendants admit, based upon information and belief, that some state laws required NECC to obtain a patient-specific prescription prior to compounding medications. The Defendants admit, based upon information and belief, that NECC violated some of these laws but do not profess to be experts on the laws of other states. The Defendants affirmatively state that Tennessee law permits anticipatory compounding. *See* Tenn. Code Ann. § 63-10-204(4)(b).

173. The Defendants admit that SSC did not send individual prescriptions to NECC for the medications SSC purchased but instead provided a list of patients as requested by NECC to satisfy Mass. BoP regulations. The Defendants deny, based upon information and belief, the remaining allegations of paragraph 173.

174. The Defendants admit that SSC did not submit individualized prescriptions for each patient's injection of MPA prior to purchasing the MPA from NECC but deny that SSC was required to do so. The Defendants are without knowledge or information sufficient to form a belief as to how "many, if not all," other Clinic-Related Defendants ordered medication from NECC. However, based on the limited information received to date, it appears that multiple clinics ordered medications from NECC using the same method as SSC.

175. Denied as to these Defendants. The Defendants are without knowledge or information sufficient to form a belief as to how "many, if not all," other Clinic-Related Defendants ordered medication from NECC. However, based on the limited information received to date, it appears that multiple clinics ordered medications from NECC using the same method as SSC.

176. Denied. The Court dismissed the Plaintiffs' civil conspiracy claim as a matter of law pursuant to its August 29, 2014, memorandum decision at Dkt. 1360.

177. The Defendants admit that some state laws require compounding pharmacists to comply with United States Pharmacopeia National Formulary Standards. The Defendants deny that Tennessee was one of those states.

178. The Defendants admit, based upon information and belief, the allegations of paragraph 178.

179. Denied. In fact, NECC affirmatively represented to the Defendants that it complied with USP 797.

180. Denied.

181. The Defendants admit, based upon information and belief, that NECC was not accredited. However, the Defendants affirmatively state that NECC was subject to regulation by the FDA, the Mass. BoP, and dozens of other state boards of pharmacy that were responsible for ensuring that NECC compounded safe and effective medications. The Defendants are without knowledge or information sufficient to form a belief as to whether accreditation offers any *meaningful* assurance as to the quality and competence of compounding pharmacies granted accreditation. The Defendants affirmatively state, based upon information and belief, that Pfizer is not "accredited" by any organization that "offers independent assurance as to [Pfizer's] quality and competence."

182. Denied.

183. The Defendants are without knowledge or information sufficient to form a belief as to whether there were accredited compounding pharmacies in Tennessee that

SSC could have purchased from instead of NECC. The Defendants deny that NECC was unregistered. NECC was licensed and regulated by the Mass. BoP and dozens of other state boards of pharmacy, including the Tennessee Board of Pharmacy, and regulated by the FDA.

184. Denied.

185. Denied.

186. Admitted.

187. Admitted.

188. The Defendants deny, based upon information and belief, the allegations of paragraph 188.

189. The Defendants admit that SSC purchased preservative-free MPA from NECC. The Defendants deny the remaining allegations of paragraph 189.

190. The Defendants deny any wrongdoing and affirmatively state that they complied with the recognized standard of acceptable professional practice prior to purchasing from NECC. No physician or clinic can guarantee that every product purchased will be safe and effective for every patient.

191. The Defendants admit that the ASHP has published Guidelines on Outsourcing Sterile Compounding Services (hereinafter "Outsourcing Compounding Guidelines"). The Defendants deny the remaining allegations of paragraph 191 and specifically deny that the NECC was not regulated by the FDA. NECC fell squarely within the FDA's definition of its own regulatory authority.

192. The Defendants deny that they were required to perform the "due diligence" recommended by the ASHP Outsourcing Compounding Guidelines, and

specifically deny that they were required to take the steps identified in subparagraphs (a) through (t). The Defendants complied with the recognized standard of acceptable professional practice prior to purchasing MPA from NECC.

a. Denied.

b. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine if NECC was an accredited compounding pharmacy."

c. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "at least once annually, unannounced, visit NECC's corporate offices and compounding facilities and confer with NECC's corporate, pharmacy and compounding staff."

d. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine whether NECC had any product liability lawsuits filed against it for preparations compounded."

e. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine whether there had ever been recalls of any of NECC's compounded preparations."

f. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "evaluate NECC's standard operating procedures and manuals."

g. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "evaluate NECC's pharmacist technician training."

h. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "evaluate NECC's policies and procedures for sterility testing."

i. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "evaluate examples of batch reports for product being considered for outsourcing."

j. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "evaluate examples of quality-control reports."

k. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "obtain and evaluate history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions."

l. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter."

m. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "evaluate whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data."

n. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards." Regardless, NECC represented that it complied with USP 797.

o. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination."

p. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine whether NECC had a policy that required validation of new or changed facilities, equipment, processes, container types, for sterility and repeatability."

q. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the

handling of hazardous agents." Regardless, NECC represented that it complied with USP 797.

r. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "evaluate NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment."

s. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "evaluate NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities."

t. The Defendants deny that the recognized standard of acceptable professional practice required the Defendants to "determine whether NECC had a history of disciplinary or punitive actions by any regulatory agency."

193. The Defendants deny that the Outsourcing Compounding Guidelines set the recognized standard of acceptable professional practice and further deny that following some or all of the guidelines would, more probably than not, have changed the outcome.

194. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 194.

195. Denied.

196. The Defendants admit, based upon information and belief, the allegations of paragraph 196.

197. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 197.

198. The Defendants are without knowledge or information sufficient to form a belief as to how NECC "competed" in the "medical marketplace." The Defendants deny that the price of NECC's medications was the deciding factor in SSC's decision to purchase from NECC. The Defendants are without knowledge or information sufficient to form a belief as to the price of MPA from FDA-registered manufacturers during the relevant time period.

199. The Defendants admit that SSC purchased MPA from NECC. The Defendants deny that, prior to the outbreak, NECC was viewed as an "unsafe compounding pharmacy."

a. The Defendants admit that NECC's building was near a recycling facility, a fact that must have been known by the Mass. BoP and FDA following their investigation(s) of NECC in the years leading up to 2012.

b. The Defendants admit, based upon information and belief, that NECC did not separately compound individual doses of MPA.

c. The Defendants admit, based upon information and belief, that the MPA from the three contaminated lots was not properly sterilized but affirmatively state that the Defendants have not conducted discovery of NECC sufficient to determine the exact cause of the contamination.

d. The Defendants are without knowledge or information sufficient to form a belief as to the adequacy of NECC's quality control measures.

e. The Defendants are without knowledge or information sufficient to form a belief as to whether NECC operated in a sterile environment when compounding the three contaminated lots of MPA.

f. The Defendants admit, based upon information and belief, that it was determined after the outbreak that NECC did not submit adequate samples from the three contaminated lots of MPA to ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") for testing before releasing them for distribution.

g. The Defendants admit, based upon information and belief, that NECC did not comply with USP 797 when compounding the three contaminated lots of MPA.

h. The Defendants admit, based upon information and belief, that NECC violated various state laws but do not have knowledge or information sufficient to form a belief as to whether those laws were "designed to protect…citizens from substandard and adulterated prescription drugs."

i. The Defendants admit, based upon information and belief, that NECC contracted with UniFirst for cleanroom cleaning services. The Defendants admit, based upon conditions observed in the video from the Plaintiffs' December 2012 inspection of NECC, that UniFirst may have failed to adequately clean the cleanrooms.

The Defendants deny any and all allegations of wrongdoing and affirmatively state that they complied with the recognized standard of acceptable professional practice during all relevant times.

200. Pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, only the physician who actually performed the epidural steroid injection procedure was legally required to obtain the patient's informed consent. Accordingly, the allegations of paragraph 200 were dismissed against all Defendants except Dr. Lister. The Defendants admit that Dr. Lister did not specifically inform the Plaintiffs that SSC purchased the MPA from NECC but deny the recognized standard of acceptable professional practice required him to do so. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether Dr. Lister obtained adequate informed consent.

201. Pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, only the physician who actually performed the epidural steroid injection procedure was legally required to obtain the patient's informed consent. Accordingly, the allegations of paragraph 201 were dismissed against all Defendants except Dr. Lister. The Defendants admit that Dr. Lister did not specifically inform the Plaintiffs that SSC purchased the MPA from NECC but deny the recognized standard of acceptable professional practice required him to do so. The Defendants deny that MPA is not FDA approved. The Defendants deny that NECC was not inspected by the FDA. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether Dr. Lister obtained adequate informed consent.

202. Pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, only the physician who actually performed the epidural steroid injection procedure was legally required to obtain the patient's informed consent. Accordingly, the allegations of paragraph 202 were dismissed against all Defendants except Dr. Lister. The Defendants admit that Dr. Lister did not specifically inform the Plaintiffs that SSC purchased the MPA from NECC but deny the recognized standard of acceptable professional practice required him to do so. The Defendants deny that NECC was not regulated by the FDA. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether Dr. Lister obtained adequate informed consent.

203. Pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, only the physician who actually performed the epidural steroid injection procedure was legally required to obtain the patient's informed consent. Accordingly, the allegations of paragraph 203 were dismissed against all Defendants except Dr. Lister. The Defendants admit that Dr. Lister did not specifically inform the Plaintiffs that SSC purchased the MPA from NECC but deny the recognized standard of acceptable professional practice required him to do so. The Defendants deny that NECC was not regulated by the FDA. The Defendants deny that, categorically, drugs produced by manufacturers registered with the FDA are produced to higher quality standards than drugs produced by compounding pharmacies regulated by the FDA and in compliance with USP 797. The Defendants admit, based upon information and belief, that NECC did not comply with USP 797 and applicable law when compounding the contaminated MPA but affirmatively state that drug companies registered with the FDA also have

lapses in the manufacturing process that cause contamination. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether Dr. Lister obtained adequate informed consent.

204. Denied.

205. The Defendants deny selling MPA to the Plaintiffs. The Defendants admit, based upon information and belief, that some of the MPA administered to some Plaintiffs was contaminated with fungus. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 205. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA.

206. The Defendants deny any wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries and damages. The Defendants admit, based upon information and belief, that Dr. Lister administered MPA that was later determined to be contaminated to some of the Plaintiffs. The Defendants deny that, prior to the recall, there was any reason to suspect that the MPA was contaminated. The Defendants admit, based upon information and belief, that the contaminated MPA caused some Plaintiffs to suffer injuries and, at times, death. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA, and the Plaintiff's alleged symptoms, diagnosis, treatment, and injuries.

VI. GENERAL ALLEGATIONS

207. The Defendants deny any wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of any of the Plaintiffs' alleged injuries and damages. The Defendants admit, based upon information and belief, that the contaminated MPA caused some Plaintiffs to suffer injuries and/or damages. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA, and the Plaintiff's alleged symptoms, diagnosis, treatment, injuries, and damages.

208. The Defendants deny any wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries and damages. The Defendants admit, based upon information and belief, that the contaminated MPA caused some surviving family members to suffer injuries and/or damages. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the patient-decedent actually received contaminated MPA, and the patient-decedent's alleged symptoms, diagnosis, treatment, injuries, along with the surviving Plaintiff's own alleged injuries and/or damages.

209. The Defendants deny any wrongdoing and specifically deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries and/or damages. The Defendants admit, based upon information and belief, that the contaminated MPA caused some Plaintiffs whose spouse received the contaminated MPA to suffer damages. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the patient-

spouse actually received contaminated MPA, and the patient-spouse's alleged symptoms, diagnosis, treatment, and injuries, along with the Plaintiff's own alleged injuries and/or damages.

210. The Defendants admit, based upon information and belief, that the contaminated MPA caused some Plaintiffs whose parent received the contaminated MPA to suffer injuries and/or damages. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the patient-parent actually received contaminated MPA, and the patient-parent's alleged symptoms, diagnosis, treatment, and injuries, along with the Plaintiff's own alleged injuries and/or damages.

VII. CAUSES OF ACTION

COUNT I – NEGLIGENCE AND GROSS NEGLIGENCE (Against Liberty)

211. All responses above are incorporated herein by reference.

212. to 217. The allegations of paragraphs 212 to 217 are not asserted against the Defendants. No response is required. To the extent such allegations are proven at trial, the Defendants adopt and incorporate such allegations, and fault must be allocated to Liberty whether they are a party at trial or not.

COUNT II – NEGLIGENCE AND GROSS NEGLIGENCE (Against UniFirst)

218. All responses above are incorporated herein by reference.

219. to 225. The allegations of paragraphs 219 to 225 are not asserted against the Defendants. No response is required. To the extent such allegations are proven at

trial, the Defendants adopt and incorporate such allegations, and fault must be allocated to UniFirst whether they are a party at trial or not.

COUNT III – NEGLIGENCE AND GROSS NEGLIGENCE
(Against Clinic-Related Defendants)

226. All responses above are incorporated herein by reference.

227. The Defendants admit that the Defendants and their employees or agents involved in the Plaintiffs' epidural steroid injection procedures were required to and did comply with the recognized standard of acceptable professional practice in Crossville, Tennessee, or a similar medical community when selecting medication for the procedure and performing the procedure. The Defendants deny that Defendants not involved in the procedure and that did not select the medication owed a duty to the Plaintiffs arising from the selection of medication or the procedure. The Defendants further deny that the recognized standard of acceptable professional practice in Crossville, Tennessee, or a similar medical community required the Defendants to independently verify that NECC complied with laws regarding pharmaceuticals prior to purchasing. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding any alleged duty owed by the Defendants.

228. The Defendants admit that the Defendants and their employees or agents involved in the Plaintiffs' epidural steroid injection procedures were required to and did comply with the recognized standard of acceptable professional practice when selecting medication for the procedure and performing the procedure. The Defendants deny that Defendants not involved in the procedure and that did not select the medication owed a duty to the Plaintiffs arising from the selection of medication or the procedure. The

Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding any alleged duty owed by the Defendants.

229. The Defendants admit that the Defendants and their employees or agents involved in the Plaintiffs' epidural steroid injection procedures were required to and did comply with the recognized standard of acceptable professional practice in Crossville, Tennessee, or a similar medical community when selecting medication for the procedure and performing the procedure. The Defendants deny that Defendants not involved in the procedure and that did not select the medication owed a duty to the Plaintiffs arising from the selection of medication or the procedure. The Defendants further deny that the recognized standard of acceptable professional practice required the Defendants to independently verify that NECC "utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated or contaminated" prior to purchasing. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding any alleged duty owed by the Defendants.

230. The Defendants admit that the Defendants and their employees or agents involved in the Plaintiffs' epidural steroid injection procedures were required to and did comply with the recognized standard of acceptable professional practice in Crossville, Tennessee, or a similar medical community when selecting medication for the procedure and performing the procedure. The Defendants deny that Defendants not involved in the procedure and that did not select the medication owed a duty to the Plaintiffs arising from the selection of medication or the procedure. The Defendants

reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding any alleged duty owed by the Defendants.

231. The Defendants admit that the Defendants and their employees or agents involved in the Plaintiffs' epidural steroid injection procedures were required to and did comply with the recognized standard of acceptable professional practice when selecting medication for the procedure and performing the procedure. The Defendants deny that Defendants not involved in the procedure and that did not select the medication owed a duty to the Plaintiffs arising from the selection of medication or the procedure. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding any alleged duty owed by the Defendants.

232. Pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, only the physician who actually performed the epidural steroid injection procedure was legally required to obtain the patient's informed consent. Accordingly, the allegations of paragraph 232 were dismissed against all Defendants except Dr. Lister. The Defendants admit that Dr. Lister did not specifically inform the Plaintiffs that SSC purchased the MPA from NECC but deny the recognized standard of acceptable professional practice required him to do so. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether Dr. Lister obtained adequate informed consent.

233. Denied. Further, the Defendants affirmatively state, based upon information and belief, that Pfizer is not "accredited" by any independent organization.

234. The Defendants deny all allegations of wrongdoing and specifically deny the allegations of wrongdoing in paragraph 234, subparagraphs a. through w. The

Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of Plaintiffs' alleged injuries or damages.

235. The Defendants admit that, when SSC decided to purchase MPA from NECC, SSC's Nursing Director was an employee of SSC. The Defendants deny that Dr. Lister was an employee of SSC. He was a member of SSC. The Defendants admit that Dr. Lister administered MPA from NECC to some of the Plaintiffs. The Defendants admit that, if the Plaintiffs establish an employment or agency relationship, they may be liable for the actions of the employee or agent.

236. Denied.

237. Denied.

238. Denied.

239. Denied.

240. Denied.

241. Denied.

242. Denied.

COUNT IV – VIOLATION OF STATE CONSUMER PROTECTION STATUTES (Against Clinic-Related Defendants)

243. All responses above are incorporated herein by reference. The Defendants deny any and all liability to the Plaintiffs for any damages under the Tennessee Consumer Protection Act, and further state that, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all of the Plaintiffs' Tennessee Consumer Protection Act claims were dismissed, except for the Plaintiffs' claims for the "monies used to purchase MPA."

244. Denied.

245. Denied.

246. Denied.

247. Denied.

248. Denied.

249. Denied.

250. Denied.

251. Denied.

252. Denied.

253. Denied.

254. Denied.

255. Denied.

a. Denied.

b. Denied.

c. Denied.

d. Denied.

256. Denied.

257. Denied.

258. The Defendants deny any and all liability to the Plaintiffs for any damages under the Tennessee Consumer Protection Act, and further state that, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all of the Plaintiffs' Tennessee Consumer Protection Act claims were dismissed, except for the Plaintiffs' claims for the "monies used to purchase MPA." The Defendants reserve and do not

waive the right to respond to each individual Plaintiff's allegations regarding damages resulting from alleged violations of the Tennessee Consumer Protection Act.

259. The Defendants deny any and all liability to the Plaintiffs for any damages under the Tennessee Consumer Protection Act, and further state that, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all of the Plaintiffs' Tennessee Consumer Protection Act claims were dismissed, except for the Plaintiffs' claims for the "monies used to purchase MPA." The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding damages resulting from alleged violations of the Tennessee Consumer Protection Act.

260. The Defendants deny any and all liability to the Plaintiffs for any damages under the Tennessee Consumer Protection Act, and further state that, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all of the Plaintiffs' Tennessee Consumer Protection Act claims were dismissed, except for the Plaintiffs' claims for the "monies used to purchase MPA." The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding damages resulting from alleged violations of the Tennessee Consumer Protection Act.

261. Denied.

262. Denied.

263. The Defendants deny any and all liability to the Plaintiffs for any damages under the Tennessee Consumer Protection Act, and further state that, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all of the Plaintiffs' Tennessee Consumer Protection Act claims were dismissed, except for the Plaintiffs' claims for the "monies used to purchase MPA." The Defendants reserve and do not

waive the right to respond to each individual Plaintiff's allegations regarding damages resulting from alleged violations of the Tennessee Consumer Protection Act.

264. Denied.

265. Denied.

266. Denied.

267. Denied.

268. Denied.

269. Denied.

270. The Defendants deny any and all liability to the Plaintiffs for any damages under the Tennessee Consumer Protection Act, and further state that, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all of the Plaintiffs' Tennessee Consumer Protection Act claims were dismissed, except for the Plaintiffs' claims for the "monies used to purchase MPA." The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding damages resulting from alleged violations of the Tennessee Consumer Protection Act.

271. The Defendants deny any and all liability to the Plaintiffs for any damages under the Tennessee Consumer Protection Act, and further state that, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all of the Plaintiffs' Tennessee Consumer Protection Act claims were dismissed, except for the Plaintiffs' claims for the "monies used to purchase MPA." The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding damages resulting from alleged violations of the Tennessee Consumer Protection Act.

COUNT V – VIOLATION OF M.G.L. c.93A
(Against Liberty)

272. All responses above are incorporated herein by reference.

273. to 283. The allegations of paragraphs 273 to 283 are not asserted against the Defendants. No response is required.

COUNT VI – VIOLATION OF M.G.L. c.93A
(Against UniFirst)

284. All responses above are incorporated herein by reference.

285. to 295. The allegations of paragraphs 285 to 295 are not asserted against the Defendants. No response is required.

COUNT VII – BATTERY
(Against Clinic-Related Defendants)

296. to 298. The Court dismissed this claim by memorandum decision issued August 29, 2014, at Dkt. 1360. No response is required.

Count VIII – FAILURE TO WARN
(Against Clinic-Related Defendants)

299. All responses above are incorporated herein by reference. Additionally, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, the Plaintiffs' claims for an alleged "failure to warn" will be evaluated under the provisions of Tennessee's Health Care Liability Act governing claims for lack of informed consent. And, pursuant to the same memorandum decision, all informed consent claims against Defendants other than Dr. Lister were dismissed.

300. The Defendants deny that the acceptable standard of professional practice required SSC to purchase the MPA from a supplier other than NECC. The

Defendants affirmatively state that NECC's medications were viewed as "safe" and "medically acceptable" prior to the outbreak.

301. The Defendants admit that Dr. Lister was legally required to obtain the Plaintiffs' informed consent. The Defendants deny that the acceptable standard of professional practice in Crossville, Tennessee, or a similar medical community required Dr. Lister to inform Plaintiffs of the name of the company that manufactured each medical supply, including the steroid, used during the procedures. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether Dr. Lister obtained adequate informed consent.

302. The Defendants admit that SSC prepared a form for patients to read and sign evidencing their consent to the performance of epidural steroid injections. The Defendants admit that Dr. Lister was legally required to obtain the Plaintiffs' informed consent prior to performing their procedures. The Defendants deny that the acceptable standard of professional practice in Crossville, Tennessee, or a similar medical community required Dr. Lister to inform Plaintiffs of the name of the company that manufactured each medical supply, including the steroid, used during the procedures. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether Dr. Lister obtained adequate informed consent.

303. Denied.

COUNT IX – TENNESSEE PRODUCT LIABILITY CLAIMS
(Against Clinic-Related Defendants)

304. All responses above are incorporated herein by reference. Additionally, pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, all product liability claims against Defendants other than SSC have been dismissed.

305. The Defendants admit that some of the medications administered to the Plaintiffs at SSC were compounded by NECC. The Defendants reserve the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff received medication form NECC.

306. Admitted.

307. The Defendants admit that the section imposes an automatic stay with various exceptions. The statutory section speaks for itself.

308. The Defendants admit that the Plaintiffs could have filed suit against NECC before December 21, 2012.

309. The Defendants admit that 11 U.S.C. § 362(a)(1) operates as a stay of "the commencement or continuation, including the issuance or employment of process, of a judicial, administrative, or other action or proceeding against the debtor that was or could have been commenced before the commencement of the case under this title, or to recover a claim against the debtor that arose before the commencement of the case under this title." The statutory section speaks for itself.

310. The Defendants admit, based upon information and belief, that NECC is not presently compounding medications.

311. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 311.

312. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 312.

313. Denied.

314. Denied.

315. Admitted. The Court's order speaks for itself and has no collateral estoppel effect as to these Defendants.

316. The Defendants admit that SSC purchased MPA from NECC and that Dr. Lister administered it to some of the Plaintiffs. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA.

317. The Defendants admit, based upon information and belief, that at least some of the MPA from NECC was contaminated. The Defendants deny the suggestion that they engaged in any wrongdoing in procuring the MPA or in administering the MPA during the Plaintiffs' procedures. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA.

318. The Defendants admit, based upon information and belief, the allegations of paragraph 318. MPA purchased from NECC arrived in sealed packages containing sealed individual vials labeled as injectable. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA.

319. Denied.

320. Denied.

321. Denied.

322. Denied.

323. The Defendants deny that NECC cannot be served with process. NECC can be served with process under the Tennessee Long-Arm Statute, codified at Tenn.

Code Ann. § 20-2-225. Upon the filing of a motion for relief from the automatic stay, the Plaintiffs' claims can be pursued against NECC. The Defendants deny that the Plaintiffs can pursue product liability claims against the Defendant health care providers.

324. The Defendants deny that the Plaintiffs can pursue product liability claims against the Defendant health care providers.

325. The Defendants admit, based upon information and belief, that at least some of the MPA from NECC was contaminated. The Defendants deny the suggestion that they engaged in any wrongdoing in procuring the MPA or in administering the MPA during the Plaintiffs' procedures. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA.

326. The Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 326.

327. The Defendants deny that SSC sold or distributed MPA or that SSC breached any warranty, express or implied, to the Plaintiffs. The Defendants reserve and do not waive the right to respond to each individual Plaintiff's allegations regarding whether the Plaintiff actually received contaminated MPA.

328. Denied.

COUNT X – AGENCY
(Against the Clinic-Related Defendants)

329. to 336. The Court dismissed this claim by memorandum decision issued August 29, 2014, at Dkt. 1360. No response is required.

COUNT XI – CIVIL CONSPIRACY
(Against the Clinic-Related Defendants)

337. to 351. The Court dismissed this claim by memorandum decision issued August 29, 2014, at Dkt. 1360. No response is required.

COUNT XII – WRONGFUL DEATH
(Against Each Defendant)

352. All responses above are incorporated herein by reference.

353. No response is required to paragraph 353.

354. Denied as to these Defendants.

355. The Defendants admit, based upon information and belief, that the contaminated MPA caused injuries to some of the Plaintiffs, including death. The Defendants deny all allegations of wrongdoing and specifically deny the allegations of wrongdoing in paragraph 355. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries or damages. The Defendants reserve the right to respond to each individual Plaintiff's allegations regarding cause of death and alleged injuries and damages.

356. The Defendants deny all allegations of wrongdoing. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries or damages. The Defendants reserve the right to respond to each individual Plaintiff's alleged injuries and damages.

357. Denied as to these Defendants.

COUNT XIII – LOSS OF CONSORTIUM
(Against All Defendants)

358. All responses above are incorporated herein by reference.

359. The Defendants admit, based upon information and belief, the some of the Plaintiffs are husband and wife or parent and child. The Defendants reserve the right to respond to each individual Plaintiff's allegations regarding their relationship to one another.

360. The Defendants deny all allegations of wrongdoing. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries or damages. The Defendants reserve the right to respond to each individual Plaintiff's alleged injuries and damages.

361. The Defendants admit, based upon information and belief, that the contaminated MPA caused some Plaintiffs whose spouse or parent received the contaminated MPA to suffer injuries and/or damages. The Defendants deny all allegations of wrongdoing. The Defendants deny that any of their allegedly wrongful acts or omissions were a legal cause of the Plaintiffs' alleged injuries or damages. The Defendants reserve the right to respond to each individual Plaintiff's alleged injuries and damages.

COUNT XIV – PUNITIVE DAMAGES
(Against All Defendants)

362. All responses above are incorporated herein by reference.

363. Denied.

VIII. PRAYER FOR RELIEF

a. to g. The Defendants deny that the Plaintiffs are entitled to any recovery from them under any legal theory and specifically deny that the Plaintiffs are entitled to the recovery requested in their "Prayer for Relief."

ADDITIONAL PARAGRAPHS

1. The Defendants demand a jury of 12 to try this action.

2. Any allegation in the Plaintiffs' Complaints not admitted, denied, explained, or otherwise qualified is hereby denied.

3. The Defendants deny that they acted negligently, recklessly, or intentionally or that they proximately caused any injury that otherwise would not have occurred.

4. The Defendants affirmatively state that they complied with the laws and regulations applicable to them, and with industry standards.

5. The Defendants deny that their allegedly wrongful acts or omissions were a legal cause of the alleged injuries and specifically reserve the right to assert independent, intervening, or superseding cause as a defense. The Defendants affirmatively assert that the injuries to the Plaintiffs resulted from independent cause and did not come about, through, or as a result of any alleged wrongful act on these Defendants' part.

6. The Defendants reserve the right to amend their Answer to expand the allegations of comparative fault should discovery warrant the assertion of fault against any party or nonparty.

7. The Defendants reserve the right to amend their Answer to assert any defense or third-party complaints for indemnification not already asserted should justice so require.

8. The Defendants deny that the Plaintiffs are entitled to recover any sum of money from them under any theory of recovery.

9. The Defendants reserve the right to challenge compliance with the notice and certificate of good faith requirements of Tenn. Code Ann. § 29-26-121 and -122 consistent with the Court's ruling on previously-filed "global" motions to dismiss related to -121 and -122 and intend to file motions to dismiss at the case-specific stage. The Defendants move to dismiss previously-identified non-compliant individual Complaints and will brief this more fully at the case-specific stage or earlier, depending on the procedural plan the Court imposes.

10. The Defendants reassert the defenses and arguments set forth in their previously-filed motions to dismiss[4] and assert that the claims of the Complaints should be dismissed for the reasons set forth in those motions to the extent any claims or arguments have not been adjudicated. The Defendants move to dismiss *all* claims of the Complaints against them for failure to state a claim upon which relief can be granted as a matter of law.

11. Pursuant to the Court's August 29, 2014, memorandum decision at Dkt. 1360, the following claims have been dismissed:

a. The Plaintiffs' medical battery claims.

b. The Plaintiffs' civil conspiracy claims.

c. The Plaintiffs' claims attempting to hold the Defendants vicariously liable for the actions of NECC.

d. The Plaintiffs' product liability claims against all Defendants except SSC.

e. The Plaintiffs' claim for "failure to warn" or failure to obtain informed consent against all Defendants except Dr. Lister.

[4] Dkts. 770, 771, 774.

f. The Plaintiffs' Tennessee Consumer Protection Act claims except for claims "for the recovery of monies used to purchase MPA."

12. The Defendants specifically move to dismiss all claims of the Complaints because the allegedly wrongful conduct was not the proximate cause of the injuries complained of. The wrongful conduct described below – including, but not limited to, the wrongful conduct of NECC and its employees and agents in allowing the MPA to become contaminated – was the independent and legal cause of the injuries complained of. As such, all claims against these Defendants should be dismissed.

13. The Plaintiffs' claims should be dismissed for failure to state a claim upon which relief can be granted because the Defendants could not reasonably have foreseen that NECC would have breached governmental and industry standards and delivered a contaminated product. NECC's negligent and reckless conduct was the cause-in-fact and proximate cause of the injuries.

14. The Plaintiffs' claims should be dismissed because the various alleged wrongs were not the proximate cause of the alleged injuries. Specifically, the Defendants' alleged failure to require patient-specific prescriptions was not a proximate cause or cause-in-fact of the claimed injuries.

15. The Defendants specifically assert that this is a "health care liability action" governed by Tenn. Code Ann. § 29-26-101, *et seq.*, and the claim shall proceed pursuant to that section. Additionally, the Defendants assert they are entitled to the caps on damages and other protections under The Tennessee Civil Justice Act of 2011, specifically those found at Tenn. Code Ann. § 29-39-101, *et seq.*

16. The Defendants specifically assert that this is a "health care liability action" as defined in Tenn. Code Ann. § 29-26-101, *et seq.*, and that any claims against them should be governed by that section. Any claims against them pursuant to any other theories of recovery and all other causes of action should be dismissed.

17. The Defendants move to stay or dismiss the Complaints pursuant to Federal Rule of Civil Procedures 19(b).

18. The Defendants reserve the right to assert that the Plaintiffs' claims are barred by *res judicata*.

19. The Defendants reserve the right to assert that the Plaintiffs' claims are barred by collateral estoppel.

20. The Defendants specifically assert that the Plaintiffs' claims for product liability should be dismissed as a matter of law. The Defendants are not "sellers" as contemplated and defined by the statute. The Plaintiffs cannot maintain a product liability action against the Defendant health care providers.

21. The Plaintiffs' claims for breach of warranty fail as a matter of law. The Defendants did not sell a "good" to the patient. They provided a medical service. Additionally, the Plaintiffs did not timely provide notice of an alleged breach as required by Tenn. Code Ann. § 47-2-607(3)(a), and the Plaintiffs did not rely on any claimed warranty.

22. The Plaintiffs' request for a judgment that Tenn. Code Ann. § 29-39-102 and -104 are unconstitutional and void should be dismissed, and stricken from the Complaints. This is an inappropriate request for an advisory opinion. No judgment has been rendered. Courts should not consider the constitutionality of laws unless resolution

of a constitutional question is absolutely necessary to determine the issues in a case and adjudicate the rights of the parties. The laws are constitutional.

23. The Plaintiffs' claim for punitive damages should be dismissed as no conduct complained of rose to the level of being malicious, intentional, fraudulent, or reckless.

24. The Plaintiffs' claims against the limited liability companies should be dismissed consistent with Tenn. Code Ann. § 48-217-101(a) as members, holders of financial interests, governors, managers, employees, or other agents of an LLC do not have personal obligations and are not liable personally for the acts, debts, liabilities, or obligations of the LLC. Additionally, pursuant § 48-217-101(e), failure of the LLC to observe the usual company formalities or requirements shall not be grounds for personal liability of members, governors, managers, employees, or other agents.

25. Pursuant to Tenn. Code Ann. § 47-18-109(e)(2), the Defendants request an award of reasonable attorneys' fees and costs associated with defending the Plaintiffs' Tennessee Consumer Protection Act claims, which are "frivolous, without legal or factual merit, or brought for the purpose of harassment." To the extent the Court considers this a counterclaim pursuant to Federal Rule of Civil Procedure 13, the Defendants assert this as a specific counterclaim for reasonable attorneys' fees and costs.

AFFIRMATIVE DEFENSES

1. As a matter of law, the Defendants did not have a duty to refrain from purchasing product from NECC or compounding pharmacies.

2. As a matter of law, the Defendants did not have a duty to refrain from using compounded medications in patient care.

* * * * * * *

The following affirmative defenses shall apply only if the Defendants are found, either as a matter of law or by the trier of fact, to be "sellers" pursuant to Tenn. Code Ann. § 29-28-102(7) subject to claims of product liability:

3. The Defendants rely on the "sealed container" doctrine as an affirmative defense to the Plaintiffs' product liability claims. The Defendants received the MPA from NECC in a sealed package surrounding sealed vials, and were not in a position to test or inspect the contents of the vials or otherwise discover the contamination, and thus have no liability under Tennessee's Product Liability Act.

4. The Defendants rely on Tenn. Code Ann. § 29-28-104 as an affirmative defense to the Plaintiffs' product liability claims. The Defendants complied with all applicable federal and state statutes and administrative regulations existing at the time the MPA was manufactured, which concern the design, inspection, testing, manufacture, labeling, warning, or instructions for use of MPA. They are therefore entitled to the rebuttable presumption that the MPA was not unreasonably dangerous.

COMPARATIVE FAULT

NECC sold medications to thousands of health care providers across the country, from small rural clinics to the most well-respected and sophisticated metropolitan hospitals in the United States. Virtually all of them reasonably relied on NECC's representations, made through its professional sales force, owners, and pharmacists, that it produced medications in a sterile environment consistent with industry standards. NECC assured its customers, including the Defendants, that it complied with USP 797, the standard for sterile compounding, and that it employed state-of-the-art sterility safeguards to ensure the safety of its products. Additionally, NECC was regulated by the FDA and licensed to operate in all 50 states, with each state vetting NECC prior to granting licensure.

Thousands of health care providers – like the Defendants – reasonably concluded that NECC would provide safe and effective medications, relying on the representations of NECC and reasonably assuming that state and federal regulators tasked with inspecting and monitoring drug producers would do their jobs.

Unfortunately, while it was unknown to NECC's customers at the time, the large scale of NECC's operation was known to the FDA and Mass. BoP for years. The FDA and Mass. BoP sanctioned NECC's operations with regulatory inactivity despite repeated consumer complaints, choosing not to shut NECC down. The sheer size of NECC's operations and a slew of negligent affiliated companies, individuals, and third-party contractors combined with this colossal regulatory failure and led to the contamination of the medication that ultimately caused the 2012 fungal meningitis outbreak.

NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly

1. The Defendants assert comparative fault against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly. They individually, through employees and agents, and/or collectively, owed a duty to the Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

2. The Defendants hereby adopt and incorporate the Plaintiffs' allegations against Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin, as if stated fully herein for purposes of asserting comparative fault.

3. NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly, individually, through employees and agents, and/or collectively, breached their duty to the Plaintiffs, proximately causing the alleged injuries and damages, as further explained in the following paragraphs.

Contamination of MPA

4. The Defendants assert comparative fault against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly, individually, through employees and agents, and/or collectively, for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts and/or omissions including, but not limited to:

a. Contaminating the MPA that was eventually injected into the Plaintiffs, allegedly causing their injuries;

b. Failing to adequately sterilize the MPA that was eventually injected into the Plaintiffs, allegedly causing their injuries;

c. Failing to properly label the MPA that was eventually injected into the Plaintiffs, allegedly causing their injuries;

d. Failing to adequately inspect and test the MPA prior to distribution to ensure that it was free from contamination and safe for its intended use; and

e. Failing to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

Violation of Applicable Laws and Guidelines

5. The Defendants assert comparative fault against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly, individually, through employees and agents, and/or collectively, for proximately causing the alleged injuries and damages by negligently or recklessly failing to comply with applicable state and federal laws after multiple warnings and inspections by the FDA and the Mass. BoP.

6. Based upon information and belief, NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly violated state and federal laws including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Wholesaling drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f); and

f. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6).

7. NECC and Barry Cadden violated Tennessee pharmaceutical laws and regulations including, but not limited to:

a. Violating Tenn. Code Ann. § 63-10-305 by:

i. Engaging in conduct prohibited or made unlawful by any of the provisions of parts 2-5 of that chapter or any other state or federal laws relating to drugs or the practice of pharmacy;

ii. Engaging in dishonorable, immoral, unethical, or unprofessional conduct; and

iii. Failing to comply with duly promulgated rules of the Tennessee Board of Pharmacy ("Tenn. BoP").

b. Violating Tenn. Comp. R. & Regs. No 1140-01-.08 by:

i. Failing to submit a copy of NECC's May 24, 2011 inspection report conducted by the Mass. BoP to the Tenn. BoP; and

ii. Failing to comply with the requirements for patient counseling, patient profiling, drug regimen review, and pharmaceutical care as set forth in Tenn. Comp. R. & Regs. No. 1140-03-.01.

c. Violating Tenn. Comp. R. & Regs. No. 1140-07-.02 by failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee were free from contamination and safe for their intended use.

8. NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filling only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves prior to use;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the cleanroom used to manufacture MPA;

i. Specifically, between January 2012 and August 2012, NECC's environmental monitoring program found bacteria and mold in the cleanroom used to manufacture MPA; and

ii. NECC failed to investigate the discovery of bacteria and mold in the cleanroom.

i. Failing to seal penetrations in the cleanroom walls and ceilings in the cleanroom used to manufacture MPA;

j. Failing to repair door gaskets, seals, and floor sweeps in the cleanroom used to manufacture MPA;

k. Failing to clean the cleanroom used to manufacture MPA according to the guidelines set forth in USP 797;

l. Performing portions of the MPA manufacturing process requiring an ISO 5 environment under USP 797 in an environment not certified as ISO 5;

m. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

n. Failing to regularly clean or replace the cleanroom "tacky mats;"

o. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

p. Placing the cleanroom HVAC unit near a recycling facility;

q. Failing to clean underneath and behind equipment when cleaning the cleanroom used to manufacture MPA;

r. Failing to maintain the cleanroom ceiling and the building's ceiling above the cleanroom ceiling; and

s. Failing to maintain continuous ventilation of cleanrooms.

Product Liability and Breach of Warranties

9. The Defendants assert comparative fault against NECC, Barry Cadden, Lisa Cadden, Glenn Chin, and Joseph Connolly, individually, through employees and agents, and/or collectively for proximately causing the alleged injuries and damages by

violating the Tennessee Product Liability Act of 1978 codified at Tenn. Code Ann. § 29-28-101, *et seq.*

10. NECC, Barry Cadden, Lisa Cadden, Glenn Chin, and Joseph Connolly acted as a manufacturer as defined by Tenn. Code Ann. § 29-28-102 by compounding the MPA.

11. When the MPA left the control of NECC, Barry Cadden, Lisa Cadden, Glenn Chin, and Joseph Connolly, it was in a defective condition as defined by Tenn. Code Ann. § 29-28-102 because it was contaminated and unsafe for injection into patients like the Plaintiffs.

12. Contamination of the MPA proximately caused all injuries and damages alleged.

13. As a result, NECC, Barry Cadden, Lisa Cadden, Glenn Chin, and Joseph Connolly are strictly liable for all injuries and damages alleged.

14. Further, NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly, individually and collectively, proximately caused the alleged injuries and damages by negligently or recklessly manufacturing the MPA and breaching various express and implied warranties codified at Tenn. Code Ann. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

15. Specifically, NECC produced quarterly "Quality Assurance Report Cards" to highlight the safety and sterility of its facility and products and to ensure it was meeting the requirements of USP 797.

16. In the second quarter of 2012—the last quarter prior to the fungal meningitis outbreak—NECC's Quality Assurance Report Card indicated that "NECC meets and is in continued compliance with all applicable requirements and standards. This review exhibits that our existing quality control systems and facilities are in a state of control." This statement constituted an express warranty by NECC of the quality and sterility of its facilities and products, including MPA, in accordance with Tenn. Code Ann. § 47-2-313.

17. Barry Cadden endorsed this Quality Assurance Report Card.

18. NECC and Barry Cadden breached this express warranty by failing to ensure the quality and sterility of the MPA that was delivered to the Defendants was in accordance with the express warranty provided in its second quarter 2012 Quality Assurance Report Card.

19. NECC also provided customers with marketing materials wherein NECC made affirmative statements concerning its quality standards, quality control measures, and regulatory compliance, including representing and warranting that NECC:

a. Was compliant with "Class 10 microenvironment (barrier isolator);"

b. Was certified by the Mass. BoP;

c. Had its microenvironment validated every six months by an independent vendor;

d. Hired only trained and registered pharmacists;

e. Trained and validated its pharmacy personnel through Professional Compounding Centers of America, an independent certifying agency;

f. Re-validated all personnel on a quarterly basis;

g. Used only USP Chemicals obtained from FDA-registered facilities;

h. Sterilized all formulas through filtration or autoclaving;

i. Had all batches tested and certified for sterility by ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL"), an independent laboratory;

j. Allowed no medication to leave the NECC facility without first being tested and certified by ARL to ensure sterility and potency;

k. Allowed no medication to leave the NECC facility unless and until ARL made a definitive determination that the medication was sterile and free from contamination;

l. Abided by its Standard Operating Procedures that were "mapped against" USP 797 and complied with USP 797; and

m. Was compliant with all licensing requirements in all 50 states.

20. NECC breached one or more of these express warranties in violation of Tenn. Code. Ann. § 47-2-313.

21. NECC also knew, at the time it entered into a business relationship with the Defendants, that the Defendants had a particular purpose for which they required MPA and were relying on NECC's skill and judgment to manufacture and furnish goods suitable for that purpose in accordance with Tenn. Code. Ann. § 47-2-315.

22. NECC breached its implied warranty of fitness because it failed to deliver MPA that was suitable for the Defendants' particular purpose.

23. NECC also failed to provide MPA to the defendants that was fit for its ordinary purpose, thus breaching the implied warranty of merchantability pursuant to Tenn. Code Ann. § 47-2-314(2)(c).

Misleading Health Care Providers and Regulatory Authorities

24. The Defendants assert comparative fault against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly individually, through employees and agents, and/or collectively, for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts and/or omissions including, but not limited to:

a. Misrepresenting to health care providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines and

b. Misrepresenting to health care providers, the FDA, the Mass. BoP, and the Tenn. BoP that NECC was operating as a compounding pharmacy rather than a manufacturer.

25. On January 28, 2005, in a sworn statement on his initial application for a Tennessee pharmacy license, Barry Cadden answered "No" to the following question:

> Are there any charges involving moral turpitude or violation of pharmacy, or any other laws pending against you? Explain such charges or violations in detail; even to reporting minor infractions of pharmacy, liquor or narcotic laws [sic] regulations; include dates.

26. At the time, Barry Cadden had, at least, three pending non-public complaints before the Mass. BoP.

Breach of Standard Operating Procedures

27. Upon information and belief, NECC, NECC's employees and agents, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly failed to follow NECC's internal Standard Operating Procedures, which

were presumably designed to ensure compliance with industry standards for product safety and sterility.

GDC Properties Management, LLC

28. The Defendants assert comparative fault against GDC Properties Management, LLC ("GDC"), which owed a duty to the Plaintiffs as well as their health care providers to ensure that NECC's compounding facility was clean and safe for its intended use.

29. The Defendants hereby adopt and incorporate the Plaintiffs' allegations against GDC as if stated fully herein for purposes of asserting comparative fault.

30. GDC negligently permitted NECC to compound medications in an unsterile environment and failed to maintain the premises at 697 Waverly Street, Framingham, Massachusetts, in a "clean and sanitary manner" as required by 247 CMR 6.02(1).

31. GDC failed to maintain the building's ceiling directly above the cleanroom used to manufacture MPA.

32. GDC leased the building to NECC for the purpose of manufacturing medications with a recycling facility next door.

33. Upon information and belief, GDC leased space to the recycling facility itself.

34. GDC knowingly permitted NECC to violate Massachusetts and Federal law.

35. GDC's negligence proximately caused all injuries and damages alleged.

United States Food and Drug Administration

36. The Defendants assert comparative fault against the United States Food and Drug Administration ("FDA"), its directors, employees, and agents, including but not limited to, Margaret Hamburg, Gail Costello, Samia Nasr, Kathleen Anderson, Steven Silverman, Deborah Autor, and Alyson Saben, which owed a duty to the Plaintiffs as well as their health care providers to ensure that MPA manufactured, sold, and distributed by NECC was sterile and safe for its intended use pursuant to the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301, *et seq.*

37. The FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

38. The Defendants assert comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to take action against NECC even though the FDA had authority to do so, as asserted in its October 31, 2008, letter to NECC, which was not publicly available prior to the outbreak of fungal meningitis, and only became available after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny.

39. The FDA breached its duty, proximately causing all injuries and damages alleged, as further explained herein.

Failure to Make Information Publicly Available

40. The FDA proximately caused the alleged injuries and damages by negligently or recklessly failing to make publicly available all complaints, inspection

reports, and information gathered during its serial investigations of NECC, described herein.

41. The FDA failed to notify the Tenn. BoP and other state pharmacy boards of the potential threat to public health caused by NECC's non-public track record of regulatory non-compliance with state and federal law, and unsatisfactory results from on-site surveys.

42. To and including the time when the Defendants ordered and received shipment of the contaminated MPA from NECC, the only piece of information readily available to the public regarding NECC's history with regulatory agencies was the FDA's 2006 Warning Letter to NECC.

43. However, the Warning Letter does not mention any problems with MPA or any other steroids compounded by NECC, and it does not mention any reports of problems with the sterility of any medications compounded at NECC. The Warning Letter does not suspend the operation of NECC or mandate that NECC can no longer safely produce medications.

44. No other information regarding NECC's history with the FDA was readily and publicly available up to and including the time when the Defendants ordered and received shipment of the contaminated MPA from NECC.

45. On December 4, 2006, the FDA failed to issue a Public Health Alert to health care providers, warning them of the problems at NECC identified in the Warning Letter issued the same day.

46. To and including the time when the Defendants ordered and received shipment of the contaminated MPA from NECC, the FDA, Mass. BoP, and NECC were aware of the serious nature and extent of the repeated problems at NECC.

47. The Defendants were unaware of the serious nature and extent of NECC's problems nor reasonably should they have been aware.

Multiple Complaints and Inspections without Disciplinary Action

48. Despite the fact that the FDA's budget more than doubled during the time in question, from $1.55 billion in 2002 to $3.56 billion in 2012, the FDA proximately caused the alleged injuries and damages by failing to discipline or take action against NECC after becoming aware of NECC's failure to comply with applicable state and federal laws and manufacturing guidelines, including, but not limited to, the following incidents, which were not publicly reported prior to the outbreak of fungal meningitis, and only became public after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny:

a. In April 2002, after receiving two MedWatch reports of adverse events following injections of betamethasone compounded by NECC, the FDA inspected NECC and observed problems with sterility;

b. In July 2002, after receiving three additional MedWatch reports of two patients developing bacterial meningitis at a New York hospital following injections of MPA compounded by NECC, FDA investigators determined that NECC's sterility testing procedures were not in compliance with USP guidelines for sample size in relation to lot quantities, and the FDA testing found contamination in four of the 14 vials tested;

c. In August 2002, after receiving a report that patients developed meningitis following epidural steroid injections of MPA compounded by NECC, the FDA found bacterial contamination in five of the 16 vials tested and concluded that NECC had sterility and potency issues with MPA and betamethasone;

d. On February 5, 2003, during a joint meeting with the Mass. BoP to review NECC's inspection history and ostensibly to formulate a joint state-federal strategy for achieving safe compounding practices at the company, the FDA emphasized to the Mass. BoP the serious threat to public health posed by NECC's sterile compounding practices absent improvement;

e. Following the meeting, the FDA's own investigators recommended that NECC be enjoined from compounding medication for failing to comply with good manufacturing practices in the event that the Mass. BoP failed to take action against NECC;

f. On April 27, 2004, the FDA and the Mass. BoP conducted a joint inspection of NECC after receiving two new complaints against NECC:

i. First, a Wisconsin pharmacist reported that NECC's representative told the pharmacist that NECC needed a prescription for extra strength triple anesthetic cream, but the representative stated that the pharmacist could use the name of a staff member. NECC's representative also stated that another health care provider used a nurse's name; and

ii. Second, an Iowa pharmacist reported that NECC was advertising compounded prescription products for use by multiple patients with a single prescription.

g. On September 23, 2004, the FDA and the Mass. BoP conducted a joint inspection of NECC after receiving a complaint that NECC was compounding Trypan Blue Dye for use as a capillary stain during ophthalmic procedures, which was not an approved use;

i. During the inspection, Barry Cadden, an owner, and the pharmacist in charge at NECC, told investigators that NECC did not compound Trypan Blue until they received a prescription;

ii. But soon thereafter, investigators discovered a drawer with 189 vials of Trypan Blue and no corresponding prescriptions.

h. In November 2004, Barry Cadden admitted in a letter to the Mass. BoP, which was later shared with the FDA, that NECC had filled prescriptions for Trypan Blue using invalid patient names;

i. On June 25, 2007, the FDA received an Adverse Event Report from a physician stating that, following the administration of NECC Avastin, a patient had developed severe endophthalmitis and underwent emergency eye surgery;

j. On December 6, 2007, a physician called the FDA and reported that some vials of NECC betamethasone were discolored and his patients were having problems;

k. On June 17, 2008, the FDA and representatives of a pharmaceutical distributor met regarding concerns about NECC compounded

betamethasone being injected into spinal synovial fluid. The representatives provided the FDA with three different sized NECC vials;

l. On September 16, 2008, the FDA Center for Drug Evaluation and Research ("CDER") sent an inspection request to the New England District Office asking the office to inspect NECC;

m. The September 16, 2008, inspection request stated, "The purpose of this inspection request is to investigate the site's compounding practices. . .";

n. On October 9, 2008, the FDA's Los Angeles District Office received a complaint regarding a patient being hospitalized following an intravenous injection of NECC phosphatidylcholine. The patient developed a burning sensation, a swollen arm, a swollen hand, could not swallow food or liquid, vomited, and urinated blood. The FDA collected a sample of the NECC phosphatidylcholine to undergo a microbiological analysis and an analysis for potency and chemical contamination;

o. On October 17, 2008, the Director of Compliance for the New England District Office told the Director of the Investigations Branch for the New England District Office to make sure the inspector followed up with NECC about the October 9, 2008, complaint;

p. On November 4, 2008, the Director of Compliance for the New England District Office told the Director of the Investigations Branch for the New England District Office that CDER would like for the New England District Office to hold off on inspecting NECC;

q. On January 30, 2009, the testing results for the 2008 NECC phosphatidylcholine came back as super-potent and displaying signs of degradation;

r. On February 11, 2009, a compliance officer with the New England District Office told the Director of Compliance for the New England District Office that CDER had requested that inspectors from the New England District Office immediately go to NECC and determine if NECC is willing to recall its phosphatidylcholine;

s. The FDA did not go to NECC on February 11, 2009, or inform NECC that its phosphatidylcholine had tested super-potent and displayed signs of degradation;

t. On March 18, 2009, CDER told the New England District Office to once again hold off on inspecting NECC;

u. On September 14, 2009, CDER was notified of a complaint to the FDA that NECC was soliciting and distributing erythromycin without patient-specific prescriptions;

v. On September 17, 2009, the FDA received a complaint that NECC was selling sodium tetradecyl sulfate to a physician in North Carolina for use in treating varicose veins when there was only one commercially available product indicated for such treatment. CDER's complaint report indicated that CDER would be "issuing an assignment for NECC in the future;"

w. On September 23, 2009, the FDA received an adverse event report regarding a female of unknown age who received Genetech Avastin that had

been broken down by NECC into syringes. Following receipt of the Avastin broken down by NECC, the patient developed endophthalmitis. Genetech performed an evaluation of the lot and determined that all specifications were met, including sterility and purity;

x. On September 14, 2010, CDER employees discussed NECC's solicitation of antibiotics during a shortage. Samia Nasr, the Team Leader for the CDER Compounding Team, stated that NECC is "under our radar;"

y. On May 10, 2011, the Denver District Office informed the New England District Office that the Colorado Board of Pharmacy had issued a cease and desist order to NECC "regarding their illegal distribution of compounded drugs to hospitals in the Denver metropolitan area;"

z. On May 10, 2011, an optometrist with the U.S. Department of Veterans Affairs inquired with the New England District Office about whether Veterans Affairs could use NECC to repackage Avastin into single dose units. The optometrist's inquiry was sent to CDER;

aa. On May 11, 2011, Samia Nasr forwarded the Colorado Board of Pharmacy's action against NECC to others in CDER and stated, "Good news;"

bb. Also on May 11, 2011, the New England District Office discussed the Department of Veterans Affairs' inquiry. During the discussion, a compliance officer stated, "I didn't think they could use firms if profiles were unacceptable? NECC Framingham is profiled as a manufacturer (because we determined they are a manufacturer not a compounding pharmacy)[.]" In response, the New England District Office compliance officer responsible for NECC stated, "[Y]ou

are right. I didn't think of profiles. And you are right about the repacking, manufacturing, registering, listing and GMPs. I just spoke to Samia Nasr and she said the same thing about repacking that you did that it[']s manufacturing and not compounding.";

cc. On July 16, 2012, the Denver District Office notified the New England District Office that NECC violated the Colorado Board of Pharmacy's cease and desist order;

dd. Based on the foregoing, the FDA knew or should have known that NECC unlawfully acted as a manufacturer without registering with the FDA as required by 21 C.F.R. 207.21. The FDA knew or should have known that NECC did not fit the pharmacy exemption from manufacturer registration provided by 21 C.F.R. 207.10 as NECC was clearly manufacturing drugs outside "the regular course of the practice of the profession of pharmacy;"

ee. Despite the above, the FDA took no meaningful, substantive action.

2006 Warning Letter

49. The Defendants assert comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after issuing a Warning Letter to NECC on December 4, 2006, detailing numerous problems at NECC, including:

a. Compounding drugs without patient-specific prescriptions;

b. Compounding copies of commercially-available drugs;

c. Selling misbranded compounded drugs; and

d. Failing to correct problems with storage and sterility.

50. On January 5, 2007, NECC responded to the FDA's Warning Letter, but NECC's response letter was not publicly available up to and including the time when the Defendants ordered and received shipment of the contaminated MPA from NECC.

51. On October 31, 2008, the FDA replied to NECC's response in a third letter that was not publicly available up to and including the time when the Defendants ordered and received shipment of the contaminated MPA from NECC.

52. The FDA, based upon available information, failed to perform the follow-up inspection promised in its October 31, 2008, letter.

53. The FDA failed to take any readily apparent action against NECC after sending the December 4, 2006, Warning Letter, even though the Warning Letter threatened "additional regulatory action without further notice."

NECC's Failure to Comply with the FDA Compliance Policy Guidance on Pharmacy Compounding

54. The Defendants assert comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC despite knowledge that NECC had violated the FDA's Compliance Policy Guidance on Pharmacy Compounding in, at least, the following ways:

a. Compounding drugs in anticipation of receiving prescriptions (as evidenced by multiple complaints from state pharmacy boards as well as the FDA's own inspections);

b. Using commercial scale compounding equipment for compounding drug products (*e.g.*, ExactaMix EM2400 compounders);

c. Compounding drug products that were commercially available in the marketplace or that were essentially copies of commercially available FDA-approved drug products (as evidenced by a 2004 patent infringement lawsuit filed by Dusa Pharmaceuticals against NECC for copying a commercially available FDA-approved drug manufactured by Dusa Pharmaceuticals); and

d. Failing to operate in conformance with applicable state law regarding the practice of pharmacy (as evidenced by multiple complaints from state pharmacy boards as well as the FDA's own inspections).

Failure to Inspect Analytical Research Laboratories, Inc.

55. The Defendants assert comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to adequately inspect Analytical Research Laboratories, Inc. pursuant to the authority granted by 21 U.S.C. § 360(h), prior to November 8, 2012, when the FDA discovered multiple violations related to the testing of NECC medications, including:

a. Failing to comply with USP 71 when performing sterility and/or fungal testing on NECC products by:

i. Failing to maintain adequate documentation demonstrating the performance of Method Suitability Testing on all new NECC products tested; and

ii. Failing to ensure that NECC submitted the required number of vials for testing.

b. Failing to comply with USP 85 in performing endotoxin testing by:

i. Failing to calculate the Maximum Valid Dilution using the formula in USP 85; and

ii. Failing to ensure that each client provided the dosing information required to calculate the Maximum Valid Dilution using the formula in USP 85.

c. Failing to maintain documentation demonstrating validation of all analytical methods for testing the potency of NECC's products; and

d. Failing to conduct further investigation following 13 endotoxin testing failures that occurred between October 2010 and October 2012.

Massachusetts Board of Registration in Pharmacy

56. The Defendants assert comparative fault against the Massachusetts Board of Registration in Pharmacy ("Mass. BoP"), its directors, employees, and agents, including but not limited to, James Coffey, Stanley Walczyk, and Susan Manning, which owed a duty to the Plaintiffs as well as their health care providers to ensure that NECC compounded medication free from contamination and operated in compliance with applicable Massachusetts pharmaceutical laws pursuant to Mass. Gen. Laws ch. 112, § 32.

57. The Mass. BoP breached this duty, proximately causing all injuries and damages alleged, as further explained below.

Failure to Make Information Publicly Available

58. The Mass. BoP proximately caused the alleged injuries and damages by negligently or recklessly failing to make publicly available all complaints, inspection

reports, and information gathered during investigations regarding NECC, described herein.

59. Based upon available information, the Mass. BoP failed to notify the Tenn. BoP and other state pharmacy boards of the potential threat to public health caused by NECC's non-public track record of regulatory non-compliance with state and federal law, and unsatisfactory results from on-site surveys.

60. In 2006, the Mass. BoP entered into a formal, but non-public, consent agreement with NECC resolving complaints of adverse events involving sterility and meningitis. The consent agreement also provided, "[t]he Registrant, Licensee and the Board acknowledge that this agreement is a nondisciplinary agreement not reported to the National Association of State Board of Pharmacy or other outside agencies. . . ."

61. The Mass. BoP was aware that reporting of discipline would cause state boards to investigate and/or inquire into NECC's practices and agreed not to classify or disclose the consent agreement as a disciplinary action.

62. In 2004, Paul Cirel, attorney for NECC, argued in response to the Mass. BoP's proposed disciplinary action that such action would be "potentially fatal" to NECC's business. In a footnote, Cirel asserted, "[o]nce disclosed, the reprimand will surely result in investigations/inquiries/investigations in those other jurisdictions."

63. To and including the time when the Defendants ordered and received shipment of the contaminated MPA from NECC, the Mass. BoP, the FDA, NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly were aware of the serious nature and extent of the repeated problems at NECC.

64. None of the information regarding the Mass. BoP's serial inspections and investigations of NECC was readily and publicly available up to and including the time when the Defendants ordered and received shipment of the contaminated MPA.

65. The Defendants were unaware (nor reasonably should they have been aware) of the serious nature and extent of NECC's problems.

Multiple Complaints and Inspections without Disciplinary Action

66. The Mass. BoP proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after becoming aware of NECC's failure to comply with applicable state and federal laws and manufacturing guidelines, including, but not limited to, the following incidents, which were not publicly reported prior to the outbreak of fungal meningitis, and only became public after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny:

a. In 1999, Barry Cadden violated Mass. BoP regulations by providing a practitioner with blank prescription pads;

b. On October 27, 1999, the Mass. BoP issued an informal reprimand for Barry Cadden and NECC's distribution of blank prescription pads;

c. In 2001, the Idaho Board of Pharmacy reported to the Mass. BoP that NECC was soliciting business for drug products which should have been discontinued by the manufacturer;

d. In 2002, the Nevada Board of Pharmacy reported to the Mass. BoP that NECC was selling non FDA-approved products to physicians in Nevada;

e. Between 2002 and 2004, the Mass. BoP received complaints from the boards of pharmacy for Texas, South Dakota, Iowa, and Wisconsin, reporting that NECC was illegally soliciting out-of-state prescriptions for office use;

f. In March 2002, the Mass. BoP and the FDA conducted a joint inspection of NECC following the FDA's receipt of two MedWatch reports of adverse events resulting from injections of betamethasone compounded at NECC;

i. During the joint investigation, the Mass. BoP apparently failed to inform the FDA of the Mass. BoP's past inspections of NECC;

ii. The Mass. BoP also apparently failed to disclose positive endotoxin testing results for the implicated lot of betamethasone to the FDA.

iii. The FDA expressed serious concerns regarding the sterility of NECC's betamethasone compounding and NECC's record-keeping in the 483 report issued by the FDA following the investigation;

g. In July 2002, after receiving three additional MedWatch reports of two patients developing bacterial meningitis at a New York hospital following injections of MPA compounded at NECC, FDA investigators determined that NECC's sterility testing procedures were not in compliance with USP guidelines for sample size in relation to lot quantities, and FDA testing found contamination in four of the 14 vials tested;

h. In August 2002, after receiving a report that patients developed meningitis following epidural steroid injections of MPA compounded by NECC,

the FDA found bacterial contamination in five of the 16 vials tested and concluded that NECC had sterility and potency issues with MPA and betamethasone;

i. However, on February 5, 2003, during a meeting between the FDA and the Mass. BoP, the Mass. BoP agreed that it, rather than the FDA, would either require compliance from NECC or take action against NECC;

i. At the February 5, 2003, meeting, the FDA recommended that NECC be prohibited from manufacturing until it demonstrated the ability to make product reproducibly and dependably;

ii. Also at the February 5, 2003, meeting, the FDA warned of the potential for serious public health consequences if NECC's sterile compounding practices were not improved;

iii. The Mass. BoP did not discernibly respond to these recommendations and warnings;

iv. After the February 5, 2003, meeting, the Mass. BoP delayed more than a year before proposing a consent agreement to NECC on September 21, 2004;

v. On March 26, 2003, Paul Cirel sent a letter to Leslie Doyle, Compliance Officer, Division of Professional Licensure, Massachusetts Office of Investigations. In the letter, NECC refused to enter into the agreement;

vi. The Mass. BoP failed to proceed to a formal hearing as provided for in the consent agreement in the event of a refusal by NECC to accept the proposal;

vii. On April 27, 2004, the FDA and the Mass. BoP conducted another joint inspection of NECC after receiving two new complaints against NECC;

1. First, a Wisconsin pharmacist reported that NECC's representative told the pharmacist that NECC needed a prescription for extra strength triple anesthetic cream, but the representative stated that the pharmacist could use the name of a staff member. The representative also stated that another health care provider used a nurse's name;

2. Second, an Iowa pharmacist reported that NECC was advertising compounded prescription products for use by multiple patients with a single prescription.

viii. On September 21, 2004, more than two years after the first reported cases of meningitis and other adverse events, the Mass. BoP voted to seek a public censure and probation of NECC for its misconduct leading to the infections;

ix. On September 30, 2004, the Mass. BoP sent three non-disciplinary advisory letters to NECC related to complaints from pharmacists in Iowa, Wisconsin, Texas, and a surgery center in Rapid City, South Dakota. The advisory letters for the South Dakota, Iowa, and

Wisconsin complaints stated that the Mass. BoP's investigations revealed that Barry Cadden and NECC were soliciting out-of-state prescriptions for office use and using a form unapproved by the Massachusetts Department of Public Health and the Mass. BoP;

x. On October 4, 2004, the Mass. BoP sent a consent decree to NECC related to the Mass. BoP's investigation of NECC's contaminated MPA. The consent decree, if agreed to, would have imposed censure and probation, along with monitoring requirements, for three years;

xi. On November 8, 2004, NECC and Barry Cadden admitted to filling prescription orders that utilized repetitive patient names;

xii. On November 11, 2004, NECC and Barry Cadden sent a letter to the Mass. BoP refusing to agree to the proposed consent decree. NECC and Barry Cadden wrote to Mass. BoP asking it to instead consider non-public disciplinary action, to better protect NECC's business interests;

xiii. The Mass. BoP voted on November 23, 2004, to decline NECC's request for modification of the consent decree. The consent decree was then referred for formal action to prosecuting attorneys within the Massachusetts Department of Public Health;

xiv. The prosecuting attorneys at the Massachusetts Department of Public Health did not hold a hearing, opting instead to pursue negotiations with NECC.

j. On September 23, 2004, the FDA and the Mass. BoP conducted a joint inspection of NECC after receiving a complaint that NECC was

compounding Trypan Blue Dye for use as a capillary stain during ophthalmic procedures, which was not an approved use;

i. During the inspection, Barry Cadden told investigators that NECC did not compound Trypan Blue until they received a prescription;

ii. But soon thereafter, investigators discovered a drawer with 189 vials of Trypan Blue and no corresponding prescriptions;

iii. In November 2004, Barry Cadden admitted to the Mass. BoP that NECC had filled prescriptions for Trypan Blue using invalid patient names.

k. Neither the Mass. BoP nor the Massachusetts Department of Public Health prosecuting attorneys took any disciplinary action against NECC until January 2006. In January 2006, Mass. BoP approved a negotiated consent agreement that was referred to as "non-disciplinary," and provided for a suspended period of non-public probation. The agreement required NECC to submit to two inspections by a third-party evaluator over a six-month period. The agreement also provided that Mass. BoP would "not report[] to the National Association of State Board of Pharmacy[5] or other outside report agencies;"

l. On January 30, 2006, the Mass. BoP received an initial audit from Pharmacy Support, Inc., an independent evaluator, reporting that NECC was not in substantial compliance with USP 795 or USP 797. The audit noted the following deficiencies:

i. Documentation practices were inadequate;

[5] The letter incorrectly refers to the National Association of Boards of Pharmacy as the National Association of *State* Board of Pharmacy."

ii. Written procedures were admittedly not followed routinely;

iii. Procedures were not in strict accordance with USP standards;

iv. End product testing was often performed on stock solutions and not the end product as required; and

v. Validation of sterilization cycles and media fills was inadequate.

m. On April 7, 2006, the Mass. BoP received Pharmacy Support, Inc.'s final report, which concluded that NECC needed to redesign Cleanroom 1 in order to achieve compliance with USP 795 and USP 797;

n. On April 13, 2006, following an eight-week jury trial and three-year indictment, both Pharmacy Support, Inc.'s CEO and Chief Compliance Officer were criminally convicted on 19 counts, including fraud, mail fraud, and a violation of the Food and Drug Control Act;

o. On December 4, 2006, the FDA issued a Warning Letter to NECC detailing numerous problems at NECC including:

i. Compounding drugs without patient-specific prescriptions;

ii. Compounding copies of commercially-available drugs;

iii. Selling misbranded compounded drugs; and

iv. Having problems with storage and sterility.

Formal Complaints Filed in 2003

67. The Defendants assert comparative fault against the Mass. BoP for proximately causing the alleged injuries and damages by negligently or recklessly failing

to discipline or take action against NECC in February 2003 after issuing formal complaints against NECC identifying serious problems including:

a. Failing to follow sterility guidelines and procedures;

b. Failing to follow record-keeping requirements;

c. Failing to follow batch record-keeping requirements;

d. Failing to provide certificates of analysis;

e. Failing to provide proof of sterility testing;

f. Failing to provide endotoxin test results;

g. Failing to provide batch numbers; and

h. Failing to provide prescriptions upon request.

68. However, the Mass. BoP failed to pursue any disciplinary action against NECC that would actually correct these problems despite the Mass. BoP investigator having performed a follow-up inspection in late February 2003 and recommending a formal reprimand.

2011 Report from the Colorado Board of Pharmacy

69. The Defendants assert comparative fault against the Mass. BoP for proximately causing the alleged injuries and damages by negligently or recklessly failing to shut down, or even inspect NECC, after receiving notice from the Colorado Board of Pharmacy on July 26, 2012, that NECC had violated a Cease and Desist Order issued by the Colorado Board of Pharmacy prohibiting NECC from selling medications in Colorado prior to receiving patient-specific prescriptions.

70. In November 2012, James Coffey, the Director of the Mass. BoP, was terminated for failing to investigate NECC following receipt of the report from the State

of Colorado, and for covering up the Mass. BoP's receipt of the July 26, 2012, report from the Colorado Board of Pharmacy.

Tennessee Board of Pharmacy

71. The Plaintiffs have alleged that the Defendants had a duty to inspect NECC's facilities prior to purchasing medications, had a duty to determine NECC's history of recalling medications, had a duty to investigate NECC's history with the FDA and Mass. BoP, and otherwise had a duty to perform due diligence in investigating and selecting NECC.

72. Because of these allegations the Plaintiffs make against these Defendants, the Defendants assert comparative fault against the Tennessee Board of Pharmacy ("Tenn. BoP"), which had the legal authority to inspect NECC, which was doing business in Tennessee as a licensee of the Tenn. BoP.

73. The Defendants assert comparative fault against the Tenn. BoP in order to avoid waiver of the issue under Rule 8(c) of the Federal Rules of Civil Procedure and the Tennessee Supreme Court's decision in *George v. Alexander*, 931 S.W.2d 517, 520-21 (Tenn. 1996).

74. If it is established that the Tenn. BoP breached its duty by failing to timely investigate and bring charges against NECC for the violations outlined herein, failing to inquire of the Mass. BoP regarding actions against NECC, or failing to inspect NECC's facility, the Defendants assert fault against the Tenn. BoP.

75. The Plaintiffs have alleged the Defendants, as private health care providers, had the duty to fully investigate and inspect NECC before doing business with it in Tennessee. Based upon these allegations, the Defendants plead the fault of

the Tenn. BoP and assert that any findings of fault against the Defendants for failure to act reasonably in choosing NECC be compared against any fault found on the part of the Tenn. BoP for failing to comply with its duty to evaluate and license NECC.

Tennessee Department of Health

76. Likewise, based upon specific allegations in the complaints, the Defendants are required to assert comparative fault against the Tennessee Department of Health ("Tenn. DoH") for any claims arising from an alleged failure to notify the Plaintiffs of their potential exposure to contaminated MPA prior to September 28, 2012.

77. The Defendants assert comparative fault against the Tenn. DoH in order to avoid waiver of the issue under 8(c) of the Federal Rules of Civil Procedure and the Tennessee Supreme Court's decision in *George v. Alexander*, 931 S.W.2d 517, 520-21 (Tenn. 1996).

78. The Defendants allege that the Tenn. DoH's actions were a cause-in-fact or a substantial factor in causing the Plaintiffs' alleged injuries arising from the alleged failure to warn.

79. From the time the Defendants learned of potential exposure, they worked closely with the Tenn. DoH to respond appropriately, particularly in the first days of this complicated and fluid outbreak. The Defendants relied on the Tenn. DoH for advice on contacting patients and responded to the outbreak both consistent with and in tandem with the Tenn. DoH, and within the acceptable standards of professional practice.

80. The Defendants promptly complied with all instructions from the Tenn. DoH and CDC regarding contacting patients, including an initial directive from the Tenn. DoH not to mention meningitis.

81. The Defendants relied upon and promptly complied with all directives and guidance received from the Tenn. DoH related to this fungal meningitis outbreak.

82. If it is established that the Tenn. DoH did not recommend appropriate notification of patients, the Defendants are constrained to assert comparative fault against the Tenn. DoH.

Medical Sales Management, Medical Sales Management SW, John Notarianni, and Mario Giamei

83. The Defendants assert comparative fault against Medical Sales Management ("MSM"), Medical Sales Management SW ("MSMSW"), John Notarianni, and Mario Giamei who, individually and collectively (and acting as employees/agents of NECC MSM and/or MSMSW), owed a duty to the Plaintiffs and their health care providers to provide truthful information regarding the safety and sterility of NECC's products and NECC's compliance with applicable state and federal law and USP guidelines.

84. The Defendants hereby adopt and incorporate the Plaintiffs' allegations against GDC as if stated fully herein.

85. MSM, MSMSW, John Notarianni, and Mario Giamei breached this duty, proximately causing all injuries and damages alleged, as further explained in the following paragraphs.

86. The Defendants assert comparative fault against MSM, MSMSW, John Notarianni, and Mario Giamei, individually and collectively, for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts and/or omissions including, but not limited to:

a. Misrepresenting to health care providers that NECC's products were safe and sterile;

b. Misrepresenting to health care providers that NECC's manufacturing facilities and processes complied with USP guidelines; and

c. Failing to adequately train and/or supervise John Notarianni and/or Mario Giamei in the advertising, selling, and/or distribution of NECC's medications.

Product Liability and Breach of Warranties

87. In addition to, and in the alternative of, Defendants' product liability claims against NECC, Barry Cadden, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, and Joseph Connolly, the Defendants assert comparative fault against MSM, MSMSW, John Notarianni, and/or Mario Giamei, individually, through employees and agents, and/or collectively for "selling" NECC MPA and violating the Tennessee Product Liability Act of 1978 codified at Tenn. Code Ann. § 29-28-101, *et seq.*

88. The Plaintiffs have alleged that NECC is not subject to service of process pursuant to 11 U.S.C. § 362(a)(1).

89. On July 24, 2013, the United States Bankruptcy Court for the District of Massachusetts in *In re: New England Compounding Pharmacy, Inc.*, Case No. 12-19882-HJB, ordered that NECC is insolvent and has been insolvent since December 21, 2012 (Dkt. No. 397).

90. When the MPA left the control of NECC, it was in a defective condition as defined by Tenn. Code Ann. § 29-28-102 because it was contaminated and unsafe for injection into patients like the Plaintiffs.

91. MSM, MSMSW, John Notarianni, and/or Mario Giamei were engaged in the business of selling NECC MPA.

92. MSM, MSMSW, John Notarianni, and/or Mario Giamei sold NECC MPA to the Defendants.

93. MSM, MSMSW, John Notarianni, and/or Mario Giamei are sellers as defined by Tenn. Code Ann. § 29-28-102(7).

94. As a result of Defendants' inability to serve NECC and NECC's insolvency, MSM, MSMSW, John Notarianni, and/or Mario Giamei are strictly liable for the Plaintiffs' injuries pursuant to Tenn. Code Ann. §§ 29-28-106(4) and (5) and Tenn. Code Ann. § 29-28-101, *et seq.*

95. MSM, MSMSW, John Notarianni, and/or Mario Giamei, individually and collectively, proximately caused the alleged injuries and damages by negligently or recklessly breaching various express and implied warranties codified at Tenn. Code Ann. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

ARL Bio Pharma, Inc.

96. The Defendants assert comparative fault against ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") which owed a duty to the Plaintiffs and their health care providers to properly test medications submitted by NECC that would eventually be administered to the Plaintiffs by their health care providers.

97. The Defendants hereby adopt and incorporate the Plaintiffs' allegations against ARL as if stated fully herein.

98. ARL breached its duty to the Plaintiffs and their health care providers, proximately causing all injuries and damages alleged, as explained in the following paragraphs.

99. The Defendants assert comparative fault against ARL for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts and/or omissions including, but not limited to:

a. Failing to discover contamination in the three contaminated lots of MPA from NECC, lots 05212012@68, 06292012@26, and 08102012@51;

b. Failing to comply with guidelines governing the testing of NECC's medications including, but not limited to:

i. Failing to comply with USP 71 when performing sterility and/or fungal testing on NECC products by:

1. Failing to maintain adequate documentation demonstrating the performance of Method Suitability Testing on all new NECC products tested; and

2. Failing to ensure that NECC submitted the required number of vials for testing.

ii. Failing to comply with USP 85 when performing endotoxin testing by:

1. Failing to calculate the Maximum Valid Dilution using the formula in USP 85; and

2. Failing to ensure that each client provided the dosing information required to calculate the Maximum Valid Dilution using the formula in USP 85.

iii. Failing to maintain documentation demonstrating validation of all analytical methods for testing the potency of NECC's products; and

iv. Failing to conduct further investigation following 13 endotoxin testing failures that occurred between October 2010 and October 2012.

UniFirst Corporation, d/b/a UniClean Cleanroom Service

100. The Defendants assert comparative fault against UniFirst Corporation, d/b/a UniClean Cleanroom Service ("UniFirst") which owed a duty to the Plaintiffs and their treating health care providers to exercise reasonable care when contracting with NECC to clean NECC's facility and when cleaning the facility.

101. The Defendants hereby adopt and incorporate the Plaintiffs' allegations against UniFirst as if stated fully herein.

102. UniFirst breached its duty to the Plaintiffs and their health care providers proximately causing the Plaintiffs' alleged injuries as more fully described in the following paragraphs.

103. As a company specializing in cleanroom cleaning, UniFirst knew or should have known the guidelines set forth in USP 797 for cleanroom cleaning.

104. UniFirst knew or should have known that the cleaning required by its contract with NECC did not satisfy USP 797.

105. Further, UniFirst employees or agents negligently performed the cleaning required by UniFirst's contract with NECC.

106. The acts or omissions described above proximately caused the Plaintiffs' alleged injuries.

Liberty Industries, Inc.

107. The Defendants assert comparative fault against Liberty Industries, Inc. ("Liberty") which owed a duty to the Plaintiffs and their health care providers to exercise reasonable care and follow all applicable laws and standards during the manufacture, construction, installation, design, certification, and ongoing maintenance of NECC's cleanrooms.

108. The Defendants hereby adopt and incorporate the Plaintiffs' allegations against Liberty as if stated fully herein.

109. Liberty breached its duty to the Plaintiffs and their health care providers, proximately causing all injuries and damages alleged.

Victory Mechanical Services, Inc. and Victory Heating & Air Conditioning Co., Inc.

110. The Defendants assert comparative fault against Victory Mechanical Services, Inc. and Victory Heating & Air Conditioning Co., Inc. (collectively, "Victory") which owed a duty to the Plaintiffs and their health care providers to exercise reasonable care and follow all applicable laws and standards during the manufacture, construction, installation, design, certification, and ongoing maintenance of NECC's ventilation system.

111. The Defendants assert comparative fault against Victory for proximately causing the alleged injuries and damages by negligently or recklessly committing various acts and/or omissions including, but not limited to:

a. Failing to discover visible contaminates in NECC's ventilation system;

b. Failing to properly maintain NECC's ventilation system;

c. Failing to properly install NECC's ventilation system;

d. Failing to maintain sterility in NECC's cleanrooms during maintenance on NECC's ventilation system;

e. Failing to ensure that NECC's ventilation system could withstand the stresses of being placed in close proximity to a recycling facility;

f. By committing other violations as shall be revealed in discovery.

112. Victory's negligence proximately caused all injuries and damages alleged.

Scientific Air Analysis, Inc.

113. The Defendants assert comparative fault against Scientific Air Analysis, Inc. ("SAA") which owed a duty to the Plaintiffs and their health care providers to exercise reasonable care and follow all applicable laws and standards during its inspection and certification of NECC's cleanrooms. SAA had a duty to withhold certification from NECC if NECC's cleanrooms did not comport with applicable laws and industry standards. SAA had a duty to report NECC's compounding of large quantities of medications without proper FDA registration.

114. Upon information and belief, SAA certified NECC's cleanrooms every six months, including in June 2012.

115. SAA breached its duty to the Plaintiffs and their health care providers by failing to identify and correct, or require NECC to correct, problems in NECC's cleanrooms that caused the contamination of the MPA at issue, prior to certifying NECC's cleanrooms in June 2012.

116. If NECC's facility was in as poor condition as the Plaintiffs allege when the contaminated MPA was compounded, SAA observed or should have observed those poor conditions when it certified NECC's cleanrooms in June 2012. As a result, SAA should have refused to certify NECC's cleanrooms and/or should have reported the condition of NECC's facility to the Mass. BoP and/or the FDA.

117. SAA further breached its duty to the Plaintiffs and their health care providers by failing to identify and report that NECC was engaged in the illegal and risky process of producing and marketing large quantities of compounded medications without registering with the FDA.

118. SAA's negligence proximately caused all injuries and damages alleged.

Pharmacy Support, Inc.

119. The Defendants assert comparative fault against Pharmacy Support, Inc. ("PSI") which owed a duty to the Plaintiffs and their health care providers to exercise reasonable care and follow all applicable laws and standards during its inspection and evaluation of NECC.

120. In 2006, PSI inspected NECC and issued two reports regarding NECC's compliance with pharmaceutical standards.

121. On April 7, 2006, PSI submitted its final report and negligently found that NECC was largely compliant with pharmaceutical standards.

122. On April 13, 2006, following an eight-week jury trial and three-year indictment, both PSI's CEO and Chief Compliance Officer were criminally convicted on 19 counts, including fraud, mail fraud, and a violation of the Food and Drug Control Act.

123. Based largely PSI's final report, the Mass. BoP found that NECC had complied with the terms of its consent agreement.

124. PSI failed to identify and report that NECC was engaged in producing and marketing large quantities of compounded medications without registering with the FDA as a drug manufacturer.

125. PSI's negligence proximately caused all injuries and damages alleged.

Professional Compounding Centers of America

126. The Plaintiffs allege that NECC engaged in the illegal and risky process of producing and marketing large quantities of compounded medications and that, as a result, the Defendants should not have purchased from NECC.

127. Based upon the allegations of the Complaints, the Defendants assert comparative fault against Professional Compounding Centers of America ("PCCA"), which, upon information and belief, trained NECC's compounding employees and agents, sold NECC the recipe for preservative-free MPA, sold NECC some or all of the bulk ingredients for the preservative-free MPA, and sold NECC a policy and procedure manual.

128. PCCA advertises itself as a complete resource for a compounding pharmacy's fine chemicals, devices, equipment, training and support.

129. PCCA had a long history of working with NECC and knew or should have known that NECC was bulk compounding.

130. PCCA owed a duty to the Plaintiffs and their health care providers as consumers of NECC's products to exercise reasonable care in dealing with NECC.

a. PCCA breached this duty when it negligently trained and certified NECC's employees and agents in sterile compounding.

b. PCCA further breached its duty to the Plaintiffs and their health care providers by selling large quantities of base chemical products to a compounding pharmacy that PCCA knew or should have known was bulk compounding in violation of federal and state law.

c. Provided training to NECC's employees and agents that furthered their ability to bulk compound in violation of federal and state law.

131. PCCA's negligence proximately caused all injuries and damages alleged.

Medisca

132. The Plaintiffs allege that NECC engaged in the illegal and risky process of producing and marketing very large quantities of compounded medications.

133. Based upon the allegations of the Complaints, the Defendants assert comparative fault against Medisca, which, upon information and belief, sold large quantities of base chemicals to NECC, making this bulk compounding possible.

134. As NECC's supplier, Medisca knew or should have known that NECC was not registered with the FDA as a drug manufacturer.

135. The sheer amount of base chemicals ordered by NECC should have alerted Medisca to NECC's illegal and risky compounding of large quantities of medications.

136. Medisca owed a duty to the Plaintiffs and their treating health care providers, as foreseeable consumers of NECC's products, to report NECC's illegal practices to the FDA and/or the Mass. BoP.

137. Medisca's breached this duty knowingly, recklessly, or negligently failing to report the volume of NECC's production to the appropriate regulatory agency.

138. Medisca's breach proximately caused the Plaintiffs' alleged injuries and damages.

CALISHER & ASSOCIATES, INC.

139. The Plaintiffs allege that it was negligent for SSC to purchase MPA from NECC, and specifically allege that the Defendants had a duty to inspect NECC's facilities prior to purchasing medications, had a duty to determine NECC's history of recalling medications, had a duty to investigate NECC's history with the FDA and Mass. BoP, and otherwise had a duty to perform additional investigation of NECC before purchasing medication from NECC.

140. Because of these allegations, the Defendants assert comparative fault against Calisher & Associates, Inc., SSC's management company, which was contractually obligated to:

a. "contract for clinical and medical services and items necessary for the provision of medical care at [SSC]…including, without limitation, pharmaceuticals…and medical supplies and inventories,"

b. "oversee and coordinate the purchase…of…inventory and supplies," and

c. establish and implement policies and procedures designed to "promote [SSC's] compliance with all material certification and accreditation requirements, and all other material federal, state and local requirements."

141. The Defendants assert comparative fault against Calisher & Associates, Inc. in order to avoid waiver of the issue under Rule 8(c) of the Federal Rules of Civil Procedure and the Tennessee Supreme Court's decision in *George v. Alexander*, 931 S.W.2d 517, 520-21 (Tenn. 1996).

142. Should the jury find that these Defendants acted negligently or are otherwise liable for any of the injuries alleged in the complaints, the Defendants rely on the doctrine of comparative fault and assert that their fault should be compared against the fault of Calisher & Associates, Inc.

Additional Parties Known and Unknown

143. The Defendants further rely upon the doctrine of comparative fault, to the extent that the discovery or proof in this cause should reveal that the direct and proximate cause, or a contributing cause, of any injury or damage to the Plaintiffs was any act or omission by any person or entity which is a party to this litigation, as well as any person or entity not a party to this litigation. The Defendants reserve the right to amend their answer to assert specific conduct of parties to this action or other persons, as the facts become more fully known through discovery.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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* Admitted pursuant to MDL Order No. 1.
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CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 30th day of September, 2014.

/s/ Chris J. Tardio
Chris J. Tardio